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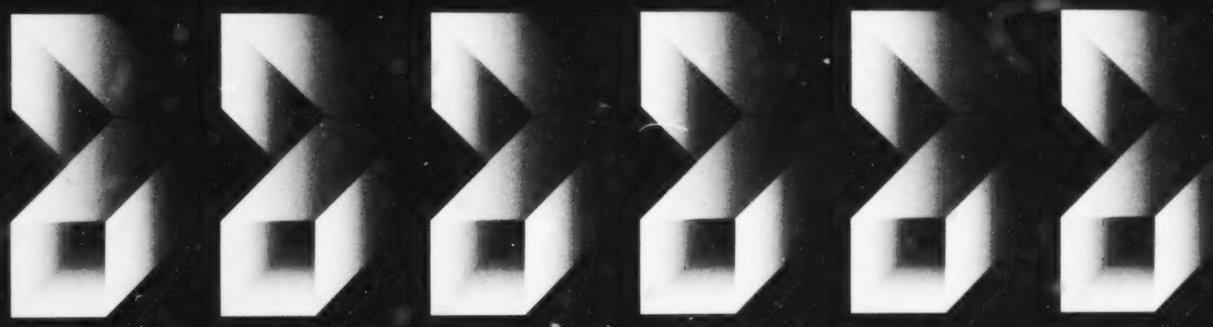

EVALUATION OF THE ENVIRONMENTAL HAZARDS PROGRAM

October 1996

Canada

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Evaluation Chronology

• Planning Completed	May 1994
• Field Work and Consultations Completed	April 1995
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Credits

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SUMMARY

This report on the evaluation of Health Canada's Environmental Hazards Program has been prepared by what is now the Evaluation Group, Strategic Planning and Review Directorate, Policy and Consultation Branch, Health Canada, in accordance with terms of reference approved by the Health Canada Audit and Evaluation Committee in July 1993. At the time the evaluation was conducted and the report drafted, the Evaluation Group was known as the Program Evaluation Division (PED); PED is the identification that will be used throughout this evaluation report.

The Environmental Hazards Program (EHP) was established to identify, assess, and manage the risks to health and safety associated with the natural and technological environment, particularly of marketed radiation-emitting and medical devices and of chemical substances. The Program's ultimate objective is to protect the health of Canadians from environmental hazards. The Environmental Hazards Program is part of one of Health Canada's four Business Lines, the Management of Risks to the Health of Canadians - Products and Disease Control. The Program also has important links with two other Business lines, Population Health Strategies for Groups at Risk and Delivery of Services to First Nations, Inuit and Yukon. Some EHP activities have received sunsetting funding from Canada's Green Plan and from Health Canada's Action Plan on Health and the Environment. The Environmental Health Directorate (EHD) of Health Canada's Health Protection Branch (HPB) is responsible for the program.

The activities of the Program may be described under the headings of risk analysis, option evaluation, and risk management.

> **Risk Analysis.** EHD officials identify hazards from microbiological agents, environmental pollutants, commercial and industrial chemicals and by-products, and radiation sources and radiation-emitting products. Program officials analyze and estimate the risks to human health arising from these hazards.
>
> **Option Evaluation.** Program officials advise and assist regulators in other Departments, agencies, and governments in the development and evaluation of risk management options.
>
> **Risk Management.** To help others manage health risks from environmental sources, EHD officials engage in the following activities:

Consultation and cooperation with other governments, departments, agencies, and non-governmental organizations (NGOs).

Provision of advice and recommendations to other governments, departments, agencies, and NGOs.

Production of information and publications and advice to individual readers of the public.

Monitoring and evaluation of hazards and exposure levels.

The following evaluation questions were approved for this program evaluation in the study's Terms of Reference in July 1993.

The design and rationale of the program.

1. To what degree does the program use the Health Protection Branch's risk assessment/risk management framework in planning and conducting its operations? How does the framework contribute to the coherence, effectiveness and efficiency of the program? Are there modifications or improvements needed to the way the program implements the framework?

2. Are there things the Environmental Health Directorate (EHD) should do to help improve the availability of, EHD access to, or quality of information a) on the toxicity and b) on actual or potential exposure to, environmental hazards assessed under the Canadian Environment Protection Act and the Radiation Emitting Devices Act?

3. *Coordination with other federal departments and agencies, and the provinces.* Do adequate mechanisms exist to ensure productive coordination, ensure overall cost effectiveness where responsibilities are shared, and avoid overlaps and duplication?

Program effectiveness.

4. What have been the program's achievements in assessing substances on the Priority Substances List? What have been the consequences of these assessments?

   a. How many assessments have been completed?

b. What health hazards were identified? How serious were the hazards? What has or might have been the extent of public exposure to these hazards?

c. What consultations did EHD conduct to discuss control implementation strategies?

d. What regulations, guidelines, or standards did EHD recommend as a result of these consultations? Have these been promulgated? If not, why not?

e. What indicators can be developed, or are already available, to illustrate how these assessments might contribute to a reduction in human morbidity and mortality rates or lead to an increase in the quality of life of Canadians?

5. What is the effectiveness of EHD's administration of the Radiation Emitting Devices Act and Regulations?

   a. How does the annual planning and resourcing of this activity reflect the Department's health risk assessment and management strategy?

      1. Is there an adequate system for identifying and assessing high-risk devices, after the devices are marketed and in operation, as well as before?

      2. Are there significant risks from radiation emitting devices that EHD is unable to manage adequately?

   b. What is the extent of industrial and institutional compliance with regulatory actions and decisions taken under the Radiation Emitting Devices Act? Are there problems with the enforcement of these actions and decisions?

   c. Are there aspects of the administration of the Radiation Emitting Devices Act and Regulations that should be changed, dropped, or replaced with alternate approaches?

6. How effectively does the program communicate with specific interest groups and with the general public about actual public exposure to radiation and chemical hazards, and known health risks from such exposure?

7. What contributions does the Environmental Hazards Program make to protecting the health and safety of Canadians?

    a. EHD provides information and advice to governments, departments, agencies, and others to help them manage the health risks from environmental sources.

        1. Do client decision makers get timely and needed information from EHD on health risks, for making risk management decisions?

        2. Does EHD provide the information in a useful format?

        3. If EHD didn't provide this information and advice, where would those clients turn for information and advice? What would be the consequences if this were to happen?

    b. What indicators can be developed, or are already available, to illustrate how the program might contribute to a reduction in human morbidity and mortality rates or lead to an increase in the quality of life of Canadians?

As agreed in the terms of reference, the Program Evaluation Division collected evidence on the evaluation questions using four main sources: documents, files and reports provided by program officials; interviews with program staff; interview and survey work conducted under contract by Resource Futures International (RFI); and case studies conducted under contract by Michael Holliday and Associates. The evaluation findings may be summarized under two broad headings: Program Design and Operation, and Program Effectiveness.

PROGRAM DESIGN AND OPERATION

A. Planning under the Risk Management Framework

The development of the risk management framework began in 1984 with the work of an inter-departmental working group on risk management analysis, involving the federal Agriculture, Fisheries and Oceans, Environment and Health departments. The framework was then applied to and elaborated for the Environmental Hazards Directorate's working process. In 1990 the framework was extended for use throughout the Health Protection Branch.

The risk management framework seems to be working well at the level of individual projects within the Program. However, there is scope for better use of the framework in planning at the Program and Directorate levels.

There are two bureau within EHD that administer the Environmental Hazards Program: the Bureau of Chemical Hazards (BCH), and the Radiation Protection Bureau (RPB). These Bureaux plan and conduct their work in Project Areas. The Bureaux operate a matrix project system in which resources from more than one Division within the Bureaux can be applied to individual Project Areas. The Bureaux conduct annual reviews of their Project Areas, as part of their risk assessment and risk management activities. Included in these reviews are the achievements towards goals per fiscal year, progress to date of the current fiscal year, and a list of publications and information about other types of outputs. Goals and resources are also proposed for the upcoming fiscal year. The 1994/95 Project Area Reviews from the Bureau of Chemical Hazards added a logic chart that relates the activities of the Bureau to that of the risk assessment and risk management phases of the framework.

Most Program officials told PED the risk management framework is a useful tool in the planning and operation of the Program. In preparing and reviewing project plans, managers are able to relate their resources on various projects to the different parts of the framework. The risk management framework helps managers and staff understand how their projects relate to one another, where some changes might be beneficial, and where there might be opportunities for efficient cooperation and resource-sharing.

However, the framework's concepts are not used in all of the planning activities of the Directorate. For example, EHD documents do not seem to make a formal connection between the Directorate's allocation of resources and the framework. EHD's annual Project Area Review documents do not formally state relative priorities or mention a process for setting priorities across projects. It can also be argued that long-range planning of human resources should be tied in with the different phases of the framework.

PED is concerned about career and succession planning for the EHP's expert staff, both in BCH and in RPB. In some of the science disciplines represented in the program, it can take years to develop and nurture the necessary expertise and to provide the necessary collegial support, backup and succession planning. This is a challenge to senior program managers operating under the current fiscal and staffing realities of the Federal Government. Recently HPB and the Public Service Commission have begun a management development program that addresses career development and succession planning for HPB's management levels.

The principles of the framework were used in setting priorities among forty-nine major health issues during the Health Protection Branch's 1993 program review. The program review also used the principles in the framework in identifying priorities for various Project Areas and programs. PED understands that HPB is repeating the application of risk management principles to priority setting in allocating resources. Several EHP projects were cancelled as a result of this exercise.

Program officials indicated that it not always clear how the framework could be used to set priorities for the Program. The framework can not be used to set priorities in a vacuum. For Priority Substances List (PSL) assessments under the Canadian Environmental Protection Act (CEPA), priorities are already set by the substances having been placed on the Priority Substances List. EHP priorities must take into account the demands of clients and stakeholders (including the Minister and the provinces) as well as the program staff's judgment of priorities. Provinces sometimes request advice and assessment work that may not be an existing Directorate priority. Furthermore, it is expected there will be increasing demands on EHD to give short-term priority requests for health advice for impact assessments under the Canadian Environmental Assessment Act (CEAA); EHD may have little or no control over the priority placed on these requests. There needs to be a balance among the legislatively-mandated priorities for the EHP, particularly when conflicting demands are made on the same limited resources.

Program officials commented that EHD's Program Area Reviews (PARs) are missing a feedback mechanism; such a mechanism should be part of this annual planning process. Although not explicit in the framework, indicators of projects' success in meeting objectives should to be added to the PAR process. PED understands efforts to do this are under way in EHD.

All Program officials interviewed were of the opinion that there has to be client and stakeholder involvement in the selection of priorities for the Program. Some of the BCH Programs have already initiated consultations with clients and stakeholders by holding meetings to discuss with clients improvements to the Program. Such meetings had been very useful to the Bureau, and BCH is planning to continue having such meetings every two to three years.

Risk perception and client/stakeholder involvement are in principle part of the risk management framework. Some CEPA documents show early stakeholder involvement for the PSL II selection process. Also, several documents prepared by the Great Lakes Health Effects Program (GLHEP) show continuous involvement of clients and stakeholders. The UV program in RPB has consulted with clients and stakeholders concerning the wording of UV risk communication messages.

B. Program Coordination with Other Programs and with Clients and Stakeholders

Officials of the Environmental Hazards Program must coordinate their activities with a daunting range of clients and stakeholders. For the interviews conducted by RFI, EHD identified fifteen "must interview" federal client departments and agencies and eleven non-government organizations from a much longer list of potential NGO clients. The program coordinates with all the provinces and territories through numerous federal-provincial committees and working groups. The Director General of EHD told PED that, at last count, he is a member of 116 different departmental, interdepartmental, intergovernmental, or inter-sectoral committees, many of which he has no personal time to meet with and to which he must send delegates from the Directorate.

Representatives of federal and provincial departments and agencies dealing with environmental hazards and human health and safety told RFI they are satisfied that EHP's activities and initiatives are moderately to well-coordinated, with very good or improved working relationships. EHD officials are seen as very cooperative in providing information and assistance and as working well with the provinces in harmonizing legislation and preparing guidelines. EHD is seen as a credible, objective, science-based advisor that puts health effects in the proper perspective and context. Overlaps and duplication were not an issue in the view of these clients and stakeholders, given the highly specialized and unique expertise the program has in many areas.

A common complaint expressed in interviews with EHP officials is the response time they are given to reply to documents. Environment Canada was particularly criticized for not giving EHP officials adequate time to review and reply to draft documents (often including cabinet submissions). PED was told that BCH "does not have the staff compliment to attend all the meetings or review all the documents generated by the Department of the Environment." All program officials interviewed commented that a reduction in the number of formal mechanisms and committees and an increase in the number of informal mechanisms could lead to better coordination.

Interview respondents from other parts of Health Canada see opportunities for improvement of coordination with the EHP. Some BCH and Health Promotion Division (HPD) officials noted there has been poor coordination and communication between some parts of the two organizations. However, there have been good links in the past between some officials in the HPD and in the GLHEP. Some working-level officials in both organizations think there could be benefits to both organizations from more regular coordination of their efforts.

Some of the CEPA assessments under PSL I did not contain sufficient information on human exposure levels and exposure routes to support the development of control options. Such information is hard to obtain and is not always available. It is important for CEPA assessments to focus on estimates of human exposure to environmental hazards and on the relationships between sources of these hazards and human exposure to them (exposure routes). Lack of analysis of how a substance enters the environment and how Canadians are exposed to it makes it difficult to decide on the most effective ways of controlling it. A national tissue bank could help monitor exposure levels and trends.

It is important to have better coordination of federal research efforts in the environmental health area and more input from the EHP into the Department's directed research programs, such as the National Health Research and Development Program (NHRDP). EHP's input has been sought on specific proposals to NHRDP related to the EHP. Senior program officials do have regular contact through the advisory committee for the NHRDP. However, officials throughout EHP (including those who sit on the advisory committee) expressed puzzlement at how NHRDP funding priorities are set.

After completing the PSL I assessments, Environmental Substances Division of BCH developed a paper identifying all the important research needs identified in the PSL process. Copies of this paper were provided to NHRDP and to the Canadian Centre for Toxicology. It is too early to say whether this paper will influence research priorities in those agencies.

There are some successful EHP partnerships with research agencies external to Health Canada. One is the St. Lawrence Health Effects project, which has established good links between NHRDP, the BioRegional Health Effects Division, the FSLQ (Quebec's counterpart to NHRDP) and several Quebec universities. Another success story for EHP is its involvement in the Eco-Research Program, an interdisciplinary program involving the Medical Research Council, the Natural Sciences & Engineering Research Council, and the Social Sciences & Humanities Research Council.

C. Developing and Reporting Indicators of Program Effectiveness

The best Health Canada can do in finding indicators of the effectiveness of the EHP is to look for evidence of the program's contribution to a reduction in the exposure of Canadians to environmental hazards. One must make a "leap of faith," albeit a reasonable one, that a reduction in exposure will translate ultimately into health benefits for Canadians. Direct demonstration of those health benefits would be difficult or impossible and would take decades to show up in mortality and morbidity statistics.

Many health effects resulting from exposure to environmental contaminants, notably carcinogens, do not show in the human body until years or even decades after the exposure to the contaminant. Many health effects linked to environmental contaminants are also linked with non-environmental factors that can be hard to measure and control in epidemiological studies. Demonstrating a direct causal relationship between delayed health effects and most of the operations of the Environmental Hazards program (or the operations of environmental programs of other governments) is thereby rendered virtually impossible, certainly within the lifetime of most programs and governments.

For example, CEPA assessments, and EHP's contributions to those assessments, contribute to the health of Canadians very indirectly. The health-risk assessment information in the CEPA documents will inform and guide the development of control strategies. The administration of these strategies will, one hopes, reduce human exposure to toxic substances, which over time will presumably improve the health of Canadians, or at least prevent adverse health affects that might otherwise have been developed. The measurement and demonstration of these health effects through changes in morbidity and mortality statistics would at best take decades to accomplish and would be problematic to prove or link back to the Program's efforts under CEPA.

Balancing the cost of the EHP against direct or indirect health benefits is a problematic calculation in these circumstances. Even if the health effects could be readily and unambiguously quantified and attributed to the program, there remain difficult value judgments about the relative importance to be given, for example, between a substance which has the potential to mildly irritate a significant proportion of the population (but otherwise has no foreseeable health effect) and one that has the potential to cause one premature death in 1,000,000 after a lifetime of exposure.

These are not questions of merely academic or philosophical importance; with governments facing severe deficit-reduction pressures, programs such as EHP face increasing competition from other health-related programs for shrinking budgets. Though scientifically defensible measurements and computational algorithms to support cost-benefit comparisons among such programs do not seem to exist, decisions implying such comparisons and trade-offs are going to be made. As an alternative to the rigorous proof that does not and may never exist, decision makers need to be given and to consider the best available indicators of the severity of health problems the program addresses, the value the program adds to reducing or solving these problems, and the costs entailed. The development and analysis of such information requires specialized expertise not available among EHD's staff at the time this evaluation was conducted. PED understands that EHD began staffing action in 1996 for a health economist.

Officials throughout both Bureaux of EHD are aware of the importance of developing a range of indicators of their program's direct and indirect effects and benefits. This was a recurring theme in all our interviews with them. Program officials invited to attend showed strong interest and participation in the indicators workshop RFI conducted for PED as part of the evaluation; participation extended from the Director General down the organization chart to research scientists from various parts of the Directorate. RFI's report on the workshop summarizes the various indicators of the effectiveness of the EHP that were suggested.

PROGRAM EFFECTIVENESS

A. Health-Risk Assessments under the Canadian Environmental Protection Act (CEPA)

The Environmental Health Directorate's Bureau of Chemical Hazards (BCH) has important responsibilities under CEPA for assessing risks to human health from substances on the Priority Substances List (PSL). The first PSL (PSL I) contained 44 substances. With Environment Canada, Health Canada succeeded in meeting its February 1994 deadline for publishing PSL Assessment Reports on all 44 substances.

The feedback PED has received on the quality of the published PSL I assessments has been uniformly, and strongly, positive. The scientific consultants to the evaluation team report the assessments are scientifically defensible, of "outstanding" quality, and identify major health hazards with informed scientific judgments of their degree.

However, there is concern regarding the Program's ability to continue to meet CEPA assessment workloads and deadlines with current resource levels, especially in light of the sunsetting of Green Plan funding for CEPA. Balanced against this concern is the likelihood that the burden of proof for toxicity (and hence some of the BCH's workload) will shift from EHD to users and producers of priority substances, as the government amends CEPA in its response to the June 1995 recommendations of the House Standing Committee on Environment and Sustainable Development.

There are serious scientific and technical difficulties confronting Program staff in conducting CEPA assessments. It is very difficult to find good information on how, and how much, humans are exposed to PSL substances. It can be very difficult to estimate reliably the health effects of exposure to PSL substances, since many of these health effects can take years to show up reliably in mortality or morbidity statistics. It will be very difficult to compare and justify the potential health benefits with the potentially expensive costs of controlling PSL substances.

It was decided early in the PSL I assessment process to focus on risk analysis and to defer the development of control strategies until after completion of the assessments.

The reasons for this were the insufficiency of resources to permit working both on toxicity assessments and on control strategies at the same time, as well the desire to avoid unnecessary work on control options for substances that eventually were decided not to be CEPA-toxic. However, the lack of analysis in the assessment reports of how a substance enters the environment and how Canadians are exposed to it will make it difficult to decide on the most effective ways of controlling the substance.

The House of Commons Standing Committee on Environment and Sustainable Development reported in June 1995 several concerns that it has with the present PSL assessment process under CEPA. The Committee makes a number of recommendations concerning changes to the "rules of evidence" under CEPA which it believes might strengthen the Government's ability to protect human health and to promote sustainable development.

B. Effectiveness of Program Activities under the Radiation Emitting Devices (RED) Act

The administration of the Radiation Emitting Devices Act and Regulations are the responsibility of the Radiation Protection Bureau (RPB). Generally, clients and stakeholders of RPB, both within and beyond Health Canada, appear satisfied with the services provided by RPB. Information provided by RPB is generally considered of high quality, useful and timely. RPB's technical expertise in the area of ionizing and non-ionizing radiation is well recognized and sought.

Various documents reviewed by PED reflect positively on the effects on the health of Canadians resulting from the RPB's operations under the RED Act. There is evidence that exposure has been reduced in RPB-inspected remote locations from 1975 to 1994. There is evidence that RPB's advice and expertise has indirectly contributed to the reduction of unnecessary radiation from diagnostic devices used by physicians and dentists under Provincial jurisdiction.

The evaluation did not find any problems with industry compliance with the RED Act and Regulations. RPB deals with a mature, large industry that is eager to comply with the RED Act and Regulations. The industry uses its compliance with the RED Act and Regulations as a marketing tool; customers are willing to purchase products they know to be in compliance with the Act and Regulations. RPB has had a few cases where some companies did not comply with the RED Act and Regulations; these companies are now either in compliance or are no longer in business. The interviews conducted for PED by Resource Futures International (RFI) confirmed these assessments of compliance with the RED Act and Regulations.

RPB believes the RED Act has served the Canadian public well. A program official commented, "if there were no RED Act, Canada would get substandard radiation-emitting devices dumped on its market, as happens in third world countries." Interviews with external Program clients and stakeholders did not produce any concerns about the RED Act and Regulations. However, some regulatory affairs officials suggested to PED that a review of the Act would be timely and useful.

The Holliday and Associates case study of RPB's response to certain problems with Cobalt-60 radiation therapy devices found RPB communicated promptly when its advice was sought; RPB supplied technical reports described by the case study authors as being of high quality, demonstrating in-depth knowledge of the equipment and the requirements of the treatment centres. However, the case study recommended that EHD explore, in concert with other regulatory entities (both within Health Canada and outside), the possibilities of providing more regulatory attention to the safety of the patient undergoing radiation therapy treatment.

RPB's Non-Ionizing Radiation Section identifies potential health hazards and assesses health risks associated with exposure to electromagnetic fields, light or sound; it also aims at minimizing unnecessary exposure to these agents when they have been found hazardous. There are several areas where the Non-Ionizing Section is addressing popular concerns about effects of non-ionizing radiation on human health. In the judgment of RPB, only one of these concerns - exposure to ultraviolet radiation - represents a real health hazard. For the other public concerns - extremely low frequency magnetic fields, cellular telephones, police radars, video display terminals, airport noise and microwave ovens - there is no evidence of actual risk connected with exposure to these devices or agents. However, the high degree of public concern about some of these products requires the provision of advice and education, either to make the population aware of actual risks and the means to reduce them, or to allay unfounded fears.

While this program evaluation study was in progress, RPB commissioned a review of its National Radioactivity Monitoring Network and Reactor Monitor Network by an independent consulting firm. PED has examined the review report and believes that review has satisfactorily addressed the concerns raised during the program evaluation about the program's ability to respond to nuclear emergencies.

C. Communication of Information and Advice on Health Risks (Other than under CEPA and the RED Act)

Except under the RED Act, EHP has little direct regulatory authority for controlling hazardous contaminants and other environmental health risks. The mandate for such regulatory control generally resides with other federal departments or with the provinces. EHP's role in such cases is to inform and advise other regulators on the risks to be managed and on effective ways to manage the risks. EHP has very limited mandate and capability to inform the public directly, though other programs in Health Canada (such as health promotion programs) can perform this function to some extent. Most of EHD's communication products, although available to the general public, are aimed at relatively small groups of interested readers, mostly professionals working in a specialized field.

RFI concluded from their interviews that the Program's direct advice and information to federal Departments, agencies, governments and other immediate clients is a valuable and essential national service for which there is no realistic alternative. The Holliday and Associates case studies on GLHEP and the UV Program support these views.

RFI's interviews and mail survey found the Program's communications generally less effective with the public and with interest groups and other organizations that are further removed from the Program. RFI's report notes that EHD's problem in communication arises from two objectives that, if not conflicting, at least require different skills: the provision of scientific advice to a set of sophisticated and well-informed clients, and outreach communications to the general public. EHD is aware of these problems and has begun to address them.

RFI's mail survey, which was sent to persons and organizations with interests in health and the environment but who are not immediate clients of the EHP, found only moderate awareness of the EHP and its activities or communications products and correspondingly little use of many EHP information products and services.

There is no formal mechanism to integrate Program activities and planning with those of Health Promotion and Programs Branch. This could be a useful and important link in effective risk communication with stakeholders and the public. EHD's environmental health messages could have a long-lasting impact if they were coordinated with health promotion activities by Health Canada and others.

D. Protecting the Health of Canadians

The ultimate objective of the Environmental Hazards Program is to protect Canadians from health risks in the environment. Given the diversity of environmental health hazards covered by the Program, it is difficult to make a global summary of Program contributions to protecting the health and safety of Canadians. In the abstract, one might like to estimate how many lives the Program has saved or prolonged, or perhaps estimate a dollar value of disease-and-disability-free days of life saved, and to compare these figures with the costs of the Program. In reality, the data and analytic techniques to do such calculations properly across the entire Program do not exist and perhaps never will, given the nature of the hazards, the latencies of their effects, and the often indirect impacts on health of many Program activities.

Instead, PED presents in the following report a few specific cases of contributions the Program has made. On the basis of these cases, Program Evaluation Division concludes the Environmental Hazards Program has on the whole done a commendable job of protecting the public from environmental health risks.

CHAPTER ONE: INTRODUCTION

This evaluation report has been prepared in accordance with terms of reference approved by the Health Canada Audit and Evaluation Committee in July 1993. Under the Terms of Reference, the purposes of the program evaluation described in this report are:

- To provide senior management of Health Protection Branch and Environmental Health Directorate with objective information and advice about the effectiveness of the Program's activities and services.

- To provide accountability reporting according to the Treasury Board Program Evaluation Policy (August, 1991) and the Health and Welfare Canada Program Evaluation Policy.

Program Evaluation Division (PED)[1] coordinated its initial work in this evaluation with Environment Canada's program evaluation of the Canadian Environmental Protection Act (CEPA), which was in progress when the terms of reference for the Environmental Hazards evaluation were signed. PED participated with Bureau of Chemical Hazards (BCH) officials on the steering committee for the Environment Canada evaluation of CEPA, which was completed in December 1993.

Environmental hazards are among the determinants of human health, as well as of the health of the plants and animals on which human life depends.[2] Environmental hazards do not usually produce effects on human health that are as immediately measurable and dramatic as the effects from other hazards such as disease epidemics. However, the effects do exist and in the longer term can be serious. For example, a recent study reported in the press found that people living in the most polluted US cities are 15 to 17 percent more likely to die prematurely than those in cities with the cleanest air.[3]

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[1] Program Evaluation Division was renamed and reorganized in October 1995 as part of a larger restructuring of Policy and Consultant Branch (P&CB), Health Canada. PED is now the Evaluation Group, Strategic Planning and Evaluation Division, Strategic Planning and Review Directorate, P&CB. As the first draft of this evaluation report had been completed prior to this reorganization, and as PED was the name of the organization at the time the evaluation was conducted, this evaluation report will refer to Health Canada's program evaluation unit by the older name.

[2] Evans, R.G. and Stoddart, G.L. (1994). "Producing Health, Consuming Health." *Why are Some People Healthy and Others Not? The Determinants of Health of Populations*. Editors Robert G. Evans, Morris L. Barer and Theodore R. Marmor. Aldine de Gruyter, New York.

The public are aware the environment can affect their health and are concerned about these effects.

> "Nearly one third of Canadians think that environmental pollution has affected their health in the year preceding the survey (1989) either a fair amount or very much. ... Among 14 issues affecting health that were presented in HSP90, environmental pollution ranked first in terms of need for government action: 86% of Canadians ranked environmental pollution as extremely important."[4]
>
> "As of 1990, the importance of the natural environment to health was recognized by almost all Canadians. ... When asked by the pollsters simply to rate the importance of the natural environment in helping people to be healthy, 82% thought it very important and 17% thought it somewhat important."[5]

Concern about the effect of environmental pollution on health remains at high levels. In its Winter 1992 survey, the Environmental Monitor found that 90% of respondents somewhat or strongly agree that "many peoples' long term health has probably already been affected by the pollution levels in their area." In its Winter 1994 survey, the Environmental Monitor found that nearly 60% of respondents believe their own health has definitely or likely been affected by pollution over the past few years, up from 55% in the 1992 Winter survey.

There is public support for federal involvement in environmental protection and regulation. In its first-quarter 1994 survey, the Environmental Monitor found that 80% of respondents believe that "no matter what the current state of the economy, there must be strict environmental regulation of industry as part of a structural change in the way companies do business," versus 20% saying there should be more flexibility in enforcing environmental regulations on industry because of the current economic recession. Asked whether standards and regulations on drinking water quality, forest harvesting practices and other environmental aspects should be set at the federal or the provincial level, 54% said the standards should be set federally, 41% said provincially and 4% said at both levels.

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[3] "Study finds bad air more deadly than previously suspected," by Curt Suplee, *Ottawa Citizen* March 10, 1995, p. A12.

[4] *Canada's Health Promotion Survey 1990: Technical Report*. Ottawa: Minister of Supply and Services Canada, 1993, p. 78.

[5] Ibid., p. 81.

While Program Evaluation Division was writing the first draft of this evaluation study, the House of Commons Standing Committee on Environment and Sustainable Development issued in June 1995 its report "It's About Our Health! Toward Pollution Prevention: CEPA Revisited." The authors have reviewed those portions of this report that pertain to Health Canada's involvement in PSL assessments under CEPA and have considered the Committee's conclusions and recommendations in arriving at PED's own conclusions and recommendations.

It is worth noting the emphasis the Standing Committee placed on the importance of health in its considering environmental pollution. The opening words of the title of the report ("It's About Health!") and the repetition of those words on the right-sided headers of every page in the report reflect this emphasis.

This evaluation report is divided into two sections. Section one provides background information about the evaluation and the program, including a description of the program, the evaluation questions, and the methodology and data sources used in the evaluation. Section two deals with the findings and conclusions of the evaluation, discussed under two issues: program design and operation and program effectiveness.

Terminological Note.

Throughout this report, references are made to the Department of National Health and Welfare, Health and Welfare Canada, and Health Canada; similar references are made to the Minister of Health and Welfare and the Minister of Health. In 1993 a reorganization of the federal cabinet resulted in a transfer of functions from the former Health and Welfare Canada to other departments, leaving Health Canada with an exclusively health focus. The name changes have at the time of this writing not been approved by Parliament; Health Canada still functions under the authority of the Department of National Health and Welfare Act. The authors have attempted to use the name form appropriate to the time period being examined, except where this results in cumbersome or confusing wording. For the purposes of this program evaluation report, the reader should consider the different forms of the Department's name interchangeable and the distinctions among them of minimal or no consequence.

CHAPTER TWO: PROGRAM DESCRIPTION

The Environmental Hazards Program was established to identify, assess, and manage the risks to health and safety associated with the natural and technological environment, particularly of marketed radiation-emitting and medical devices and of chemical substances. The Program's ultimate objective is to protect the health of Canadians from environmental hazards. The Environmental Hazards Program is part of one of Health Canada's four Business Lines, the Management of Risks to the Health of Canadians - Products and Disease Control. The Program also has important links with two other Business lines, Population Health Strategies for Groups at Risk and Delivery of Services to First Nations, Inuit and Yukon.

The health rationale for reducing exposure to environmental contaminants and to radiation hazards is that environmental contaminants may cause acute or chronic illness by virtue of their toxic properties, and ionizing and non-ionizing radiation can cause cancer and genetic damage, even at low doses.

Environmental in the context of the Environmental Hazards Program is quite broad, including for example man-made radiation-emitting devices and natural sources of radiation. The mandate also includes hazards at work sites, in the home, in hospitals, as well as in the natural environment. These hazards can include naturally occurring or manufactured chemical substances, as well as microorganisms and genetically-engineered microorganisms and their by-products.

Environmental Health Directorate (EHD) of Health Protection Branch (HPB) has been responsible for the program for more than twenty years. The rationale for a federal role in environmental health was recently reinforced by the House of Commons Standing Committee on Environment and Sustainable Development, which said "the Committee believes that the federal government must play an important leadership role in ensuring a minimum level of health and environmental protection for all Canadians." [6] The Committee also notes "the development of standards to control toxic substances, in particular, requires an elaborate scientific apparatus. All levels of government rely on the valuable information provided by the federal research institutes on environmental and human health. Indeed, few provinces have the resources to duplicate the scientific capability of the federal government."[7]

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[6] House of Commons Standing Committee on Environment and Sustainable Development (June 1995). "It's About Our Health! Towards Pollution Prevention: CEPA Revisited," p. 19.

[7] Ibid., p. 18.

1. MANDATE

The Program operates within a mandate established under several Acts of Parliament, namely, the Department of National Health and Welfare Act, the Hazardous Products Act (HPA), the Canadian Environmental Protection Act (CEPA), Tobacco products Act (TPCA), the Pest Control Products Act (PCPA), Hazardous Materials Information Review Act (HMIRA), the Radiation Emitting Devices Act (RED Act), the Canada Labour Code (CLC), the Atomic Energy Control Act (AECA), the Food and Drug Act and the Treasury Board Dangerous Substance Safety Standards and other Agreements. The Acts that apply to the main activities to be examined in this evaluation are the CEPA and the RED Act, the CLC and Treasury Board Standards (TBSs). Other aspects of program activity are prescribed in agreements with other agencies, such as the Canada/US Great Lakes Water Quality Agreement, the Canada-Ontario Agreement Respecting Great Lakes Water Quality, and the Canada-Quebec Entente Respecting the St. Lawrence.

The CEPA is administered by Environment Canada, which is responsible for aspects regarding harm to the environment. Health Canada is responsible for the health aspects of the Act. The CEPA requires the Minister of Health to assess the risk to human health posed by chemicals and biotechnology products and to formulate objectives, guidelines, and codes of practice with respect to the environment as it affects the life and health of the people of Canada. Both Departments are responsible for compiling a List of Priority Substances for assessment, for gathering information by conducting investigations and collecting data, and for recommending to the Governor-in-Council regulations to control toxic chemicals and additions to the list of Toxic Substances Requiring Export Notification.

In August 1990, a Memorandum of Understanding was signed with Environment Canada concerning toxic substances and CEPA. Health Canada is responsible for advising Environment Canada on all health matters relating to their responsibilities under CEPA and also agrees to establish priorities for the investigation and control of toxic substances with respect to their effects on human health.

The RED Act is administered by Health Canada and provides the authority to establish regulatory control at the time of sale or importation of any radiation emitting device not primarily designed for the production of atomic energy and controlled under AECA.

A Memorandum of Understanding with the former Department of Labour (DOL) outlines the responsibilities of Health Canada under the Canada Labour Code (CLC). The Canada Occupational Safety and Health Regulations provide authority for the registration of designated radiation emitting devices used in the workplace and for the adoption and implementation of applicable safety codes developed by the Environmental Health Directorate.

Except under the Radiation Emitting Devices Act, the Environmental Hazards Program's mandate is not regulatory, but rather advisory to other governments and federal departments and agencies that do have a regulatory role.

2. THE RISK DETERMINATION MODEL

There is growing awareness among health professionals that a totally risk-free environment is an unattainable goal. A more appropriate goal is to assess and to manage risk, rather than to eliminate risk. To help it achieve this goal, the Environmental Health Directorate developed a Risk Determination Model that was eventually adopted by all of Health Protection Branch. The Program conducts activities to protect the health of Canadians from environmental hazards through the use of a risk management approach to decision making, the Health Protection Branch's model for Risk Determination. Figure 1 shows the interrelationships of the model components

INSERT FIGURE 1 HERE

Risk Determination has two main stages: RISK ASSESSMENT and RISK MANAGEMENT. **RISK ASSESSMENT** in this model has two components: *Risk Analysis* and *Option Evaluation*.

> *Risk Analysis* consists of *hazard identification* and *risk estimation*. Both of these activities assume the collection and analysis of data. *Hazard identification* occurs through four methods: epidemiology, toxicological studies (usually on animals), clinical studies on humans (drugs), and weight of evidence studies (food, environment). *Risk estimation* occurs through analysis of epidemiological and toxicological data. Priorities among health risks are set by examining the severity of the hazard, the number of people affected, the power to control the hazard, the direct cost of the option, the economic consequences of the option, and some social, political and media consequences.
>
> *Option Evaluation* consists of *development of options* and *option analysis* . Options examined generally include regulation, economic measures, insurance or compensatory plans, levies or other cost structures, direct financial support or subsidies, and advisory measures. In analyzing options, the following are considered: how efficient is the option at reducing or preventing risk; the resources required; the capacity of industry and society to carry out the option; whether the likely results are consistent with public values; and the acceptability of the precedents set by the option.

RISK MANAGEMENT in this model consists of four components:

> *Decision to act*;
>
> *Implementation of the decision* requires the development of an implementation strategy, commitment of resources and effective risk communication with affected parties;
>
> *Monitoring and evaluation of the health risks and the consequences of decisions*; includes such activities as environmental sampling, post-market surveillance, epidemiological studies, examination of consumer complaints and adverse reaction reports, evaluation of new health-risk information as it becomes available; and
>
> *Review*, involves consideration of all current risk-related information. The evidence gained during the review process could lead to the reconsideration of any of the previous steps.

3. ORGANIZATIONAL STRUCTURE

The program structure is reflected in the Environmental Health Directorate's (EHD) organizational chart, Figure 2. The Directorate organizational structure includes the Director General's office and four Bureaux. Directorate officials also participate in sixteen advisory and consultative committees. Box 1 provides a sample of EHD's main advisory and consultative committees.

1. Committee on Environmental and Occupational Health (CEOH) including sub-committees and working groups.
2. Advisory Committee on Medical Devices (ACMD).
3. Advisory Committee on a Risk-Based Classification System (ACRBCS).
4. Great Lakes Advisory Committees (GLACs) including the Teachers' Advisory Committee, EAGLE Steering Committee, Intergovernmental Health Issues Committee and the Great Lakes Effects Program Advisory Committee.
5. Scientific Advisory Committee of Global Environmental Radiation Monitoring System of UNEP/WHO.
6. Advisory Committee on Radiological Protection to the Atomic Energy Control Board.
7. Inter-departmental Ad Hoc Committee on the Effects of Atomic Radiation.
8. United Nations Scientific Committee on the Effects of Atomic Radiation.
9. Federal-Provincial Advisory Committee on CEPA.
10 Inter-Departmental Committee on Standards Policy.
11. Consumer Policy Committee of OECD.
12. Canadian Seniors Packaging Advisory Council.
13. Promotion of Safe Design of Consumer Products for Older Consumers.
14. Childhood Injury Network.
15. WHMIS Current Issue Committee.
16. WHMIS Intergovernmental Coordinating Committee.
17. CEPA Management Committee including the Toxic Substances Committee, the Strategic Options Committee and the CEPA-FPAC Working Group on Air Quality.

1 EHD's Main Advisory and Consultative Committees

INSERT FIGURE 2 HERE

DIRECTOR GENERAL'S OFFICE. Within the Director General's Office (DGO) are Biostatistical Services and the Science and Research Group which includes Environmental Health Assessment, Legislative and Regulatory Processes, Computer Applications and Operations, Administration and Publication Services.

BUREAU OF CHEMICAL HAZARDS (BCH) concentrates on the effects on human health of chemical and microbiological agents in the environment (excluding agents directly associated with food, drugs, cosmetics and medical devices). BCH consists of four Divisions: Environmental Substance, Environmental and Occupational Toxicology, Monitoring and Criteria and Bioregional Health Effects.

- **Environmental Substance Division** provides assessment and management responsibilities under CEPA.

- **Environmental and Occupational Toxicology Division** conducts research and field studies to determine the toxic effects of chemical pollutants found in the environment, in consumer products and in the workplace.

- **Monitoring and Criteria Division** conducts research and modelling studies to estimate human exposure to chemical pollutants and microbiological agents found in the environment and in consumer products.

- **Bioregional Health Effects Division** assesses the health impacts of pollution in the Great Lakes Basin, the St. Lawrence River Basin and the Arctic. It conducts research into the health effects of pollutants and develops health-based guidelines and objectives.

RADIATION PROTECTION BUREAU (RPB) investigates, assesses and controls the risk to Canadians from all sources of ionizing and non-ionizing radiation including natural and man-made sources of radioactivity. RPB consists of three Divisions: Environmental Radiation Hazards, Occupational Radiation Hazards, and Consumer and Clinical Radiation Hazards.

- **Environmental Radiation Hazards Division**, which investigates the potential effects on the Canadian population from natural and man-made sources of environmental radio-activity and from internally-deposited radioactivity.

- **Occupational Radiation Hazards Division**, responsible for the National Dosimetry Services (NDS) and the National Dose Registry (NDR) programs **(not included in this evaluation).**

- **Consumer and Clinical Radiation Hazards Division**, responsible for regulatory activities pertaining to non-ionizing and x-ray radiation and radiopharmaceuticals pursuant to the RED Act and Regulations and the Food and Drugs Act and Regulations. A major portion of the x-ray and non-ionization radiation activities is undertaken pursuant to the CLC and Treasury Board Standards.

MEDICAL DEVICES BUREAU (NOT INCLUDED IN THIS EVALUATION)

PRODUCT SAFETY BUREAU (NOT INCLUDED IN THIS EVALUATION)

4. ACTIVITIES

The activities of the Program may be described under the headings of risk analysis, option evaluation (risk assessment components), and risk management of the Risk Determination Model.

Risk Analysis. EHD officials identify hazards from microbiological agents, environmental pollutants, commercial and industrial chemicals and by-products, and radiation sources and radiation-emitting products. Program officials analyze and estimate the risks to human health arising from these hazards.

Option Evaluation. Program officials advise and assist regulators in other Departments, agencies, and governments in the development and evaluation of risk management options.

RISK MANAGEMENT. To help others manage health risks from environmental sources, EHD officials engage in the following activities:

- Consultation and cooperation with other governments, departments, agencies, and non-governmental organizations (NGOs).
- Provision of advice and recommendations to other governments, departments, agencies, and NGOs.
- Production of information and publications and advice to individual readers of the public.
- Monitoring and evaluation of hazards and exposure levels.

5. OUTPUTS

Similarly, the outputs of the Environmental Hazards Program may be described under the headings of risk analysis (risk assessment component) and risk management.

Risk Analysis. Program officials provide advice and support to provinces, health professionals, and the public on health aspects of environmental contaminants and hazards. EHD officials produce or distribute research reports and develop instrumentation and new measurement techniques for assessing hazards.

Risk Management. Program officials provide advice and support to other departments and agencies in resolving problems under their jurisdiction. They provide monitoring services (Dosimetry, environmental monitoring), information to professionals and to the public through publications, lectures, courses, videotapes, and training manuals.

EHD officials produce guidelines (e.g., on drinking water and for the quality of radiation-emitting products). They make recommendations on air quality objectives and for standards of the design, construction, installation, and registration of radiation emitting devices and products.

EHD officials draft regulations on the importing, manufacturing, processing, release, or sale of chemical substances and radiation emitting products. They develop controls and issue use-orders on radiation-emitting products.

6. EXPECTED RESULTS

INSERT FIGURE 3 HERE

The expected results of the Program may be described as follows.

- Improvement of health risk management.
- Compliance by industries and institutions through adoption of technological solutions, product labels, or safety procedures.
- More informed decision making by workers and the public regarding personally-acceptable health risks.
- Reduction in excessive human exposure to contaminants and radiation hazards.
- Ultimately, a reduction in the human morbidity and mortality caused by exposure to environmental contaminants and radiation hazards.

Figure 3 shows the Logic Chart and causal relationship between the Activities, Outputs and expected results of the Environmental Hazards Program.

7. RESOURCES

EHD's organization and distribution of resources for fiscal year 1993/94 (initial allotments) are shown in Table 1. The Directorate went through a reorganization towards the end of 1993/94; resources were transferred to the Product Safety Bureau and to the Food Directorate from the Bureau of Chemical Hazards. Table 2 presents the preliminary estimates and distribution of resources for fiscal year 1994/95.

Table 1. Environmental Health Directorate - Budget and Resource Allocation 1993-1994.							
Bureau	FTEs (#s)	Salaries ($000)	Other Oper. ($000)	Minor Capital ($000)	Control Capital ($000)	Grants & Cont. ($000)	TOTAL ($006)
DGO	34.5	1,846	913	250	381	100	3,109
BCH	191.5	11,069	9,850	1,711			22,635
RPB	92.4	4,259	1,099	948			6,306
BMD	65.6	3,638	492	201			4,331
BPS	101	5,012	1,338	13			6,744
Total	485	25,824	13,692	3,123	381	100	43,125

Source: EHD

Table 2. Environmental Health Directorate - Budget and Resource Allocation 1994-1995.						
Bureau	FTEs (#s)	Salaries ($000)	Other Oper. ($000)	Capital ($000)	Grants & Cont. ($000)	TOTAL ($000)
Director General	39.5	1,893.9	431.7	40.5	100	1,766.2
Chemical Hazards	121.5	7,271.7	10,909.2	1,087.7		19,268.6
Radiation Protection	75.4	3,650.9	1,237.8	994.3	5	5,888.0
Medical Devices	74.6	4,547.4	2,034.9	308.6		6,890.9
Product Safety	78.0	4,159.9	2,165.8	382.0		6,707.8
Total	389.0	21,823.9	16,779.5	2,813.0	105	41,768.5

Source: EHD (preliminary estimates)

8. CLIENTS

EHD's direct clients, partners and stakeholders include:

Provinces and Territories. EHD provides advice and support to Provincial and Territorial governments and Provincial institutions on health aspects of environmental contaminants and hazards. The Directorate also provides radiation safety surveillance and technical assistance for medical x-ray installations. EHD works with the provinces and territories through the Federal/Provincial Advisory Committee on Environmental and Occupational Health and through the following federal/provincial bodies:

- Sub-committee on radiation surveillance
- Sub-committee on drinking water
- Sub-committee on food and regulatory health
- Working group on bioassay and in-vivo monitoring criteria
- Working group on indoor air quality in the office environment
- Working group on recreational water quality
- Working group on blood lead intervention levels and strategies
- Multimedia Guidelines Advisory Committee.

Federal. EHD supports and provides advice to various other federal Departments, notably Environment Canada, Agriculture Canada, Transport Canada, Labour Canada, Solicitor General, Communications, the Medical Services Branch within Health Canada, and the Atomic Energy Control Board.

Industry. Drug manufacturers, radiation equipment manufacturers, the mining industry, the chemical industry and industry associations are among the main EHD clients.

Professionals. EHD publications, presentations and seminar activities provide current Canadian public health information to researchers and public health groups, including the medical profession. Workers and x-ray equipment users are also EHD clients.

NGOs. These include professional associations, universities and teaching hospitals, research centres, voluntary agencies (e.g., the Canadian Standards Association), and public interest groups.

International Agencies. EHD liaises with World Health Organization (WHO), Pan American Health Organization (PAHO), the United States' Centers for Disease Control

(CDC), the National Sanitation Foundation, the International Standards Association and many other international agencies to exchange information and expertise.

CHAPTER THREE: THE EVALUATION QUESTIONS

The following evaluation questions were approved for this program evaluation in the study's Terms of Reference in July 1993.

The design and rationale of the program.

1. To what degree does the program use the Health Protection Branch's risk assessment/risk management framework in planning and conducting its operations? How does the framework contribute to the coherence, effectiveness and efficiency of the program? Are there modifications or improvements needed to the way the program implements the framework?

2. Are there things the Environmental Health Directorate (EHD) should do to help improve the availability of, EHD access to, or quality of information a) on the toxicity and b) on actual or potential exposure to, environmental hazards assessed under the Canadian Environment Protection Act and the Radiation Emitting Devices Act?

3. *Coordination with other federal departments and agencies, and the provinces.* Do adequate mechanisms exist to ensure productive coordination, ensure overall cost effectiveness where responsibilities are shared, and avoid overlaps and duplication?

Program effectiveness.

4. What have been the program's achievements in assessing substances on the Priority Substances List? What have been the consequences of these assessments?

    a. How many assessments have been completed?

    b. What health hazards were identified? How serious were the hazards? What has or might have been the extent of public exposure to these hazards?

    c. What consultations did EHD conduct to discuss control implementation strategies?

   d. What regulations, guidelines, or standards did EHD recommend as a result of these consultations? Have these been promulgated? If not, why not?

   e. What indicators can be developed, or are already available, to illustrate how these assessments might contribute to a reduction in human morbidity and mortality rates or lead to an increase in the quality of life of Canadians?

5. What is the effectiveness of EHD's administration of the Radiation Emitting Devices Act and Regulations?

   a. How does the annual planning and resourcing of this activity reflect the Department's health risk assessment and management strategy?

      1. Is there an adequate system for identifying and assessing high-risk devices, after the devices are marketed and in operation, as well as before?

      2. Are there significant risks from radiation emitting devices that EHD is unable to manage adequately?

   b. What is the extent of industrial and institutional compliance with regulatory actions and decisions taken under the Radiation Emitting Devices Act? Are there problems with the enforcement of these actions and decisions?

   c. Are there aspects of the administration of the Radiation Emitting Devices Act and Regulations that should be changed, dropped, or replaced with alternate approaches?

6. How effectively does the program communicate with specific interest groups and with the general public about actual public exposure to radiation and chemical hazards, and known health risks from such exposure?

7. What contributions does the Environmental Hazards Program make to protecting the health and safety of Canadians?

   a. EHD provides information and advice to governments, departments, agencies, and others to help them manage the health risks from environmental sources.

      1. Do client decision makers get timely and needed information from EHD on health risks, for making risk management decisions?

2. Does EHD provide the information in a useful format?

3. If EHD didn't provide this information and advice, where would those clients turn for information and advice? What would be the consequences if this were to happen?

b. What indicators can be developed, or are already available, to illustrate how the program might contribute to a reduction in human morbidity and mortality rates or lead to an increase in the quality of life of Canadians?

Chapter Four: Data and Methods Used

1. DATA SOURCES AND METHODS

As agreed in the terms of reference and in subsequent discussions with the EHP contacts and Advisory Committee identified in those terms of reference, the Program Evaluation Division collected evidence on the evaluation questions using four main sources: documents, files and reports provided by program officials; interviews with program staff; interview and survey work conducted under contract by Resource Futures International; and case studies conducted under contract by Michael Holliday and Associates.

1.1 Data Collection and Analysis by PED Staff.

PED staff reviewed and analyzed selected EHP reports, files, data bases, and Project Area Reviews (PARs). PED staff also reviewed the other references cited in the List of References document appended to this summary report.

PED staff interviewed EHD and other Health Canada officials concerning the evaluation questions.

1.2 Contract with Resource Futures International

PED contracted with the consulting firm Resource Futures International (RFI) to undertake three information-collection exercises. The methods and results of all three exercises are described in the consulting report appended to this evaluation study (Appendix 5: Resource Futures International and the ARA Consulting Group Incorporated, May 24, 1995. *Environmental Hazards Program Evaluation Interviews, Mail Survey and Indicators Workshop: Final Report.*).

RFI interviewed representatives of the program's clients, mainly representatives of other Federal Departments and agencies, intergovernmental committees, and selected nongovernmental organizations. The organizations and initial contact persons were nominated by the EHP contacts for the evaluation and were agreed to by PED.

On April 4, 1995, RFI conducted a workshop on developing indicators of EHP program success. Invited participants included all EHP staff who had been interviewed for the evaluation, several other Health Canada staff who had been interviewed, representatives from several of the federal departments whom RFI had interviewed, the PED evaluation team, and several consultants affiliated with RFI and with Michael Holliday and Associates. Background materials were sent to participants in advance, including "Musing on Health and Environment Indicators" by M. Holliday and J. Park, prepared for PED under separate contract with Michael Holliday and Associates.

Mail Survey Methods. The ARA Consulting Group, in association with RFI, conducted a mail survey developed with PED. The findings of the survey are detailed in Appendix 5. PED developed the mailing list for this survey, and consequently the method of constructing it is not described in the consulting report. The following paragraphs provide that description.

The development of the mail survey mailing list was a complex undertaking. The master mailing list for this survey originally contained about 6100 names and addresses obtained from three different sources. The survey questionnaire was mailed to a stratified random sample of 990 addresses, selected as described below. The sampling rates varied among the three subgroups, to take into account expected differences in response rate and in the respondents' familiarity with the Environmental Hazards Program. Questionnaires were mailed in early November 1994; replies were tabulated in December 1994.

Environmental Hazards Program officials did not at the time of the evaluation maintain a single, integrated, computer-readable mailing list of all their contacts, clients and stakeholders. It was therefore necessary for PED to compile such a list with EHP assistance. This compilation took several months, as most of the lists were only in hard-copy or word-processing format, unsuitable for sampling purposes. EHP officials arranged a service contract to produce in word-processing format those mailing lists that existed only in hard copy. PED imported these lists into dBase-compatible data-base software.

BCH provided PED with a word-processing list of names and addresses taken from the mailing lists of contacts maintained by BCH's various Divisions. About 670 addresses remained after screening by PED to eliminate persons working in government departments and organizations already being interviewed by RFI. It was decided that ARA Consulting would draw a random sample of 250 addresses from this portion of the master mailing list, a sampling rate of roughly one in 2.7.

RPB provided Program Evaluation Division with a word-processing list of about 200 names, categorizing them into two groupings - frequent contacts and intermittent contacts. Of these, 83 names were identified as frequent contacts. It was decided to include in the mailing all the frequent contacts and not to include the intermittent contacts. However, in many cases there was more than one name from the same institution or organization. PED screened the list to include only one name, the most senior-ranked individual, from each institution or organization, and excluded names and addresses from government departments and organizations already being interviewed by RFI. Unfortunately, the result was a very short list of 20 addresses. It was decided to include all 20 addresses in the master mailing list.

The third source of names and addresses was a dBase-compiled mailing list maintained by regulatory affairs officials in Health Protection Branch for information letters and other regulatory announcements. Starting in 1989, HPB sent one-page questionnaires to all parties requesting information or who were already on existing regulatory affairs mailing lists. The questionnaires asked for verification of name, organization, address, an indication of health topics of interest, type of organization or institution, and professional affiliation, if any. From the data file for this mailing list (as of October 1993), PED extracted 5273 names and addresses of persons who indicated an interest in receiving information on radiation emitting devices and/or chemical hazards. PED excluded from its extract persons identifying themselves as pharmacists and veterinarians, as the EHP ordinarily does not deal with these professions. Extensive editing and cleaning of the data file was necessary; as a result of the way the original file was constructed and maintained, some individual persons and addresses appeared multiple times in the data file.

It was decided that ARA Consulting would draw a random sample of 720 names from this portion of the master mailing list, a sampling rate of roughly one in 7.3. Officials in EHD told PED they do not ordinarily use this mailing list, so it was known this portion of the list contains some persons with no direct contact with or even awareness of the Environmental Hazards program. Many of the names may never have received information or advice from the Environmental Hazards program. A lower response rate from names on this list was expected than from those on the other two lists.

Before providing the master mailing list to ARA Consulting, PED edited the merged mailing lists to eliminate duplicate names and to attempt to ensure that no more than one person (the most senior identifiable from the position title) was included from the same organization and postal code. In the case of names with addresses of universities and provincial governments, the latter rule was modified to keep only one name per department. The numbers given in the preceding paragraphs are the numbers of names remaining in the data file after completion of the editing process.

ARA Consulting drew the stratified random samples from the merged and edited dBase file PED provided to them. The identities of those persons drawn from the sample are known only to ARA Consulting and were destroyed on completion of the survey report.

The mailing list contains a very few members of the general public who appear on the larger Regulatory Affairs portion of the mailing list. As the Environmental Hazards Program does not engage in mass marketing or advertising of its activities, PED considered it would be unproductive to attempt to gauge general public awareness of EHP through an omnibus opinion survey.

Thus, the mailing lists from which the master mailing list was drawn represent two groups of clients: those individuals with whom BCH and RPB told PED they have regular contacts, and those persons who have written to HPB's regulatory affairs officials since 1989, indicating an interest in receiving information on chemical or radiation hazards.

As noted in the RFI consulting report, 32% of all names on the mailing list returned questionnaires to ARA Consulting (319 responses); 50% of the RPB names replied, 38% of the BCH names replied, and 30% of the regulatory affairs names replied. Because of the small number of RPB responses (10), these are combined in the RFI findings with the BCH responses. The analyses in that report differentiate, where appropriate, between replies from the mailing list provided by EHP officials and replies from the regulatory affairs list. Responses to the survey questions generally showed the same patterns across the two groupings of respondents.

1.3 Contract with Michael Holliday and Associates

PED contracted with the consulting firm Michael Holliday and Associates to conduct four case studies addressing selected evaluation questions.

The case studies comprised four activities or programs of the Environmental Health Directorate: BCH's preparation of CEPA assessments for PSL I substances; the Great Lakes Health Effects Program (BCH); RPB's activities in investigating the health effects of solar ultraviolet radiation; and RPB's activities with respect to Cobalt-60 radiation therapy devices manufactured by Theratronics.

The subjects of all four case studies were proposed by EHD officials in consultation with PED, and the work statements for the contract were developed jointly by PED and EHD. The contractor conducted the case studies by interviewing officials proposed by the evaluation study's EHD contacts and by reviewing documentation provided by them. The four case study reports are appended to this evaluation report:

> Appendix 1: Gunter, Alfred W. and Michael Holliday (March 22, 1995). *The Bureau of Radiation and Medical Devices Response to Problems with Theratronics Products: A Case Study*. (This study is referred to throughout this program evaluation report as "the Theratronics case study.")

Appendix 2: Park John M. and Michael Holliday (March 17, 1995). *The Environmental UV Program: A Case Study.* (This study is referred to throughout this program evaluation report as "the UV case study.")

Appendix 3: Park, John, Michael Holliday and Catherine E. Vardy (March 24, 1995). *Assessments and the Priority Substance List Under the Canadian Environmental Protection Act.* (This study is referred to throughout this program evaluation report as "the CEPA case study.")

Appendix 4: Park, John M., Michael Holliday and Catherine E. Vardy (March 15, 1995). *The Great Lakes Health Effects Program: A Case Study.* (This study is referred to throughout this program evaluation report as "the GLHEP case study.")

In addition to these four case studies, the consultant prepared a position paper on health and environmental indicators, entitled "Musings on Health and Environmental Indicators." This document was the central discussion paper for the Indicators Workshop facilitated by RFI.

Michael Holliday and Associates also contributed to the review of the first draft of the program evaluation report.

1.4 Disclaimer on Consultants' Reports.

The four case studies and the consulting report on interviews, mail survey and the indicators workshop were prepared under contract with the Program Evaluation Division (PED), Health Canada, respectively by Michael Holliday and Associates and Resource Futures International, independent consultants. **The analysis, conclusions and recommendations found in these consultants' reports are those of their authors and are not necessarily shared by the Department of National Health and Welfare.** The views of PED concerning the matters covered in these consultants' reports are expressed in the body of this PED report, "Evaluation of the Environmental Hazards Program," to which the consultants' reports have been appended.

2. INDICATORS

The indicators (evidence) used in this report to answer the evaluation questions, drawn from the data sources and methods described in the preceding section, include:

- descriptions of EHD activities, processes, and outputs;

- findings of health-risk-assessment reports;
- opinions expressed by EHD officials, other HC officials, and officials from client Departments, agencies and selected non-governmental organizations;
- survey statistics on public awareness of levels of their exposure to health hazards from the environment and on the adverse health effects arising from these hazards; and
- estimates of rates of
    - regulatory compliance, and
    - exposure to health risks from environmental sources.

Chapter Five: Program Design and Operation

This chapter examines the use of HPB's Branch's risk management framework in the planning and operation of the program and the adequacy of EHP's coordinating mechanisms.

1. Planning under the Risk Management Framework

The risk assessment/risk management framework is also known as the risk determination model or risk assessment/risk management model. For the purpose of this discussion we will refer to it either as the risk assessment/risk management framework or as the framework. Chapter Two of this evaluation report presents a more detailed description of the framework.

The early thoughts on the framework started in 1984 with the work of an Inter-Departmental Working group on risk management analysis, involving Agriculture, Fisheries and Oceans, Environment and Health. A small report was produced. In 1986, the work was pursued and included the collaboration of the Director of the Bureau of Chemical Hazards, Environmental Health Directorate. The work of the Bureau of Chemical Hazards [Health and Welfare Canada (January 1991a)], contained a much more extended version of the framework, including hazard identification, risk estimation and a description of each phase and two detailed work examples, Formaldehyde and Vinyl Chloride [Health and Welfare Canada (January 1991b)].

The framework was then applied to the Environmental Hazards Directorate's working process, and it was implemented. At that time the Assistant Deputy Minister of the Health Protection Branch became interested in the framework, and in 1990 the framework was extended to the Branch level [Health and Welfare Canada (January 1990)], [Health Canada (1993)].

The following findings are mainly based on interviews with Health Canada officials, both inside and outside the program, four case studies prepared by Holliday and Associates and commissioned by the Program Evaluation Division, and the review of related documents. The findings are presented according to: 1) the use of the framework in the planning and operation of the Program; 2) selection of priorities; 3) client/stakeholder involvement; 4) the framework's contribution to the coherence, effectiveness and efficiency of the Program; and 5) the improvements or modifications needed to implement the framework.

1.1 Use of the Framework in the Planning and Operation of the EHP

1.1.1 PED INTERVIEWS WITH HEALTH CANADA OFFICIALS

Most Program officials stated that the framework is a useful tool in the planning and operation of the Program. Interviewees said that managers are able to relate their resources on various projects to the different parts of the framework. The risk management framework helps managers and staff understand how their projects relate to one another, where some changes might be beneficial, and where there might be opportunities for efficient cooperation and resource-sharing.

Both the RPB and BCH Bureaux make use of the framework in a regular basis. The framework is used for their planned activities under their Project Area Reviews. Program officials noted that the CEPA program was structured within the context of the risk management framework. The framework is also used for unplanned activities that often result from crisis situations or requests for investigations such as the investigation of Theratronics cobalt 60 devices.

Interviewees also noted that, while the framework has served the Environmental Health Directorate and the Program well, it might need more elaboration for certain Bureaux within the Program.

The use of the framework and the PARs at the regional level might soon be a current practice. Senior EHD staff have begun meeting with Regional staff in the planning of the Project Area Reviews.

1.1.2 CASE STUDIES

GLHEP [Park et al. (March 15, 1995)]. The study found that typical GLHEP practice is to emphasize hazard identification and, where possible, then move more or less directly to risk management, bypassing formal risk estimation. To some extent risk assessment is taken out of the hands of the GLHEP by the fact that the International Joint Commission has identified regions within the Great Lakes Basin as Areas of Concern. Thus, it could be argued, these areas become by definition priorities for the program. GLHEP plays a role as a health-effects advisor in the development of Remedial Action Plans (RAPs), which correspond to the control-options phase of the framework.

CEPA [Park et al. (March 24, 1995)]. In the case of the CEPA PSL I Assessments, the study found that considerable effort was devoted to hazard identification. Some risk estimation was made for each substance for which a PSL I Assessment report was written. Full risk estimation might, as the consultants noted, have required an effort out of all proportion to the needs of risk management for the particular substance.

The consultants' report suggests that the main omission from the framework in the CEPA assessments is the consideration of the control options. The framework requires that attempts be made to weigh the costs, risk and benefits of control options. The study observed that, although the costs of a particular control option for a given toxic substance might be comparatively easy to calculate, the health benefits would be very difficult, if not impossible, to quantify.

With respect to CEPA, Program officials indicated that the Directorate is concentrating its efforts in the control option phase of the framework after completion and publication of the health risk assessment.

Theratronics [Gunther et al. (March 22, 1995)]. The case study recommends that EHD make full use of the framework in the management of risks associated with cobalt 60 teletherapy and treatment planning systems. The case study suggests this would involve proactive approaches, such as pre-market review and post-market monitoring. However, program officials note this would entail substantial resources that RPB does not have. A reviewer of the case study noted the Bureau has decided that the "relative risk of radiation therapy equipment malfunction or failure, based on problem reports and when viewed in the context of all medical devices (such as anaesthetic equipment) is not large."

UV Program [Park et al. (March 17, 1995)]. No formal risk analysis documentation was made available to the contractor for this particular case study. The UV case study noted there are major difficulties in applying the framework.

In following up on the UV case study, PED found from its interviews with Health Canada officials that hazard identification was performed by RPB in collaboration with the Laboratory Centre for Disease Control (LCDC). However, exposure to UV radiation can take decades to result in skin cancer. The UV case study reported that data on skin cancer other than melanoma are not yet registered with LCDC. Such data would have to be obtained from other sources, such as the Canadian Dermatological Association, and would therefore not be independently verifiable. Reporting practices for skin cancers such as non-melanoma skin cancers differ from province to province, increasing the uncertainty of the data. Other difficulties in risk assessment and in assessing the effects of programs to reduce human exposure to solar UV include:

- uncertainties about the relationship between emissions of ozone-depleting chemicals and actual depletion of stratospheric ozone;

- uncertainties about the mechanisms of dermatological carcinogenesis, coupled with individual differences in susceptibility;

- uncertainties about the actual extent of human exposure, relating to personal behaviour and lifestyle: in Canada; while on holidays out of Canada in sunnier climes, where UV Index figures are not available, nor are Canadian warning messages; and the lag time of several decades from exposure to onset of skin cancer.

For this particular Program, risk management equates to public risk communication. RPB has launched a successful campaign with the booklet *The Sun, Your Baby, and You.* The case study found that the Program's possible risk-management options are quite limited. RPB's standards for sunglasses and the requirement for commercial sunscreen packages to display the Sun Protection Factor (SPF) are the only regulatory options taken to date.

The UV case study report noted that "it is difficult to imagine any other realistic forms of regulation that would be effective. The only really practicable risk-management option is that of public communication, with the aim of changing public behaviour."

1.1.3 PED'S DOCUMENT REVIEW

The Bureaux of the Environmental Health Directorate plan and conduct their work in project areas. The Bureaux operate a matrix project system in which resources from more than one Division within the Bureaux can be applied to individual project areas. This ensures that expertise or knowledge in one Division can be readily made available to a project which is being led from another Division.

The Bureaux conduct annual reviews of their project areas, as part of their risk assessment and risk management activities (see Working Documents, Appendix A). Included in these reviews are the achievements towards goals per fiscal year, progress to date of the current fiscal year, and a list of publications and information about other types of outputs. Goals and resources are also proposed for the upcoming fiscal year. The process is ongoing and has been in place for the last fifteen years.

The 1994/95 Project Area Reviews from the Bureau of Chemical Hazards have now added a logic chart that reflect the activities of the Bureau to that of the risk assessment and risk management phases of the framework.

The framework's concepts, however, are not yet used in all of the planning activities of the Directorate. EHD documents do not seem to make the connection between the Directorate's allocation of resources and the framework. Recently, the Directorate prepared an internal planning document [Health Canada (July 15, 1994)] with the purpose of implementing the new line/functional authority framework and to provide an estimate of the resource requirements. Though this planning document states that the Environmental Health Directorate (Program)'s objective is achieved by identifying, assessing and managing risks to health and safety, the document does not attempt to link the organizational changes to the framework or use the framework to rationalize these organizational changes.

1.2 USE OF THE FRAMEWORK IN SETTING PRIORITIES FOR THE EHP

1.2.1 PED INTERVIEWS WITH HEALTH CANADA OFFICIALS

Program officials indicated that it not always clear how the framework could be used to set priorities for the Program. For CEPA assessment work, for example, priorities are already set by the substances having been placed on the Priority Substances List. Some noted that the framework can not be used to set priorities in a vacuum. Priorities must take into account the demands of clients and stakeholders (including the Minister and the provinces) as well as the program staff's judgment of priorities. The perceptions of the public or the media can sometimes drive EHD priorities irrationally; for example, dioxins in drinking water are a major concern among the public, but EHD officials told PED there is no evidence anyone in Canada has died yet from dioxins in drinking water. Staff contrasted this with more dramatic health effects, for example an estimated 40,000 tobacco-related unnecessary deaths in Canada each year.

In the case of BCH, some Program officials stated that there appears to be no system to prioritize the work across the Bureau and the entire Program. Since criteria have been developed for setting priorities among PSL substances, perhaps the same system for setting priorities should be used to set priorities Program-wide.

RPB officials echoed BCH comments on the difficulties in setting priorities. Often health-risk priorities for the Bureau are determined by public perception. If the public perceives a risk, then RPB has to assess it, whether or not there is scientific basis for assuming there is a problem. Public perception of risk sometimes translates into political pressure for the program to address concerns that from a scientific standpoint are not currently believed to be a problem. However, program officials note one cannot simply write off public concerns as unwarranted, as it is possible more scientific investigation could reveal evidence of a legitimate health problem.

It was suggested that RPB's risk-ranking and priority-ranking systems should mirror those in other parts of HPB, such as Drugs, Food, and Medical Devices. Within EHD, BCH rates products in four risk categories and then matches the regulatory approach to the degree of hazard. RPB does not appear to do this, and arguably should.

Program officials also indicated that the selection of priorities within the Directorate and the Program will be affected by the Canadian Environmental Assessment Act (CEAA). There is no apparent mechanisms for setting priorities under this Act. Under the Act, environmental, health and economic factors as well as public concerns are integrated into the decision-making process of any major government project. EHD/HPB's immediate participation could be required to assess the risks to human health of any of these projects.

> CEAA (Bill C-13) was passed by Parliament in June 1992. In December 1994 Bill C-56 amended the Act. CEAA is intended to ensure that whenever a federal authority proposes a physical work, that physical work not cause significant adverse environmental effects outside the jurisdiction in which the physical work is carried out, and that any environmental effects of such physical work be carefully considered before the work is undertaken. The environmental assessment is to be conducted under the direction of the Canadian Environmental Assessment Agency, reporting to the Minister of the Environment, and is to be conducted "as early as is practicable in the planning stages of the project and before irrevocable decisions are made." The Act provides for public notification of and comment on the resulting report. The Governor in Council may make regulations respecting, among other things, the time periods relating to the environmental assessment process.
>
> Though Health Canada is not explicitly mentioned in either Bill C-13 or C-56, as the federal government's health advisor the Department will be called upon to provide advice on the health implications of projects being assessed under CEAA.

In PED's interviews, Program staff expressed concerns regarding the workload implications of CEAA for the same BCH officials who are responsible for providing health risk assessments under CEPA. It appears to program officials they will be legally obligated under CEAA to produce environmental health impact assessments within short time periods. There appears to be no provision for setting priorities among requests for health advice for CEAA assessments; it appears the responses must be addressed on a "first-in, first-out" basis, regardless of the magnitude or content of the request. While CEAA assessments are not expected to be as onerous individually as CEPA assessments, the same staff must work on them and, it appears, must interrupt CEPA work in order to meet the substantially shorter deadlines. This could have a deleterious effect on BCH's ability to produce quality CEPA assessments on time. RPB staff expressed the same concern to PED about CEAA implications for their also-stretched resources.

This concern is not unique to EHP staff; it was echoed in RFI's interviews with stakeholders and clients outside the Department [Resource Futures International and the ARA Consulting Group Incorporated (May 24, 1995)], p. 9.

> "Future challenges were noted, not only with respect to PSL II, but also to the new Canadian Environmental Assessment Act (CEAA). Under CEAA, there is a deadline for scientific response. This will put increased pressure on already limited (EHD) resources; staff may have to drop what they are doing in order to respond to CEAA-driven requests."

1.2.2 CASE STUDIES

GLHEP [Park et al. (March 15, 1995)]. The study does not mention selection of priorities.

CEPA [Park et al. (March 24, 1995)]. This case study found, that for carcinogens, a rough measure of relative risk is provided by the "Exposure Potency Index" (EPI), which is given by the typical daily intake of such substance divided by the intake that would be needed to produce a five percent increase in the incidence of cancer (or other effects of exposure). EPI could in theory provide a basis for assigning priorities among such substance: the higher the EPI, the greater is the actual exposure in terms of the carcinogenic "potency"' and therefore, by this criterion, the more pressing the need to reduce exposure. However, due to the statistical and scientific uncertainties surrounding the calculation of the EPI, program officials are reluctant to use a rigid numerical calculation as a basis for assigning priorities.

Theratronics [Gunther et al. (March 22, 1995)]. The study does not mention selection of priorities.

UV Program [Park et al. (March 17, 1995)]. The study does not mention selection of priorities.

1.2.3 PED'S DOCUMENT REVIEW

There is on first examination little evidence the risk management framework is used to set priorities in the Program's planning. Project area review documents do not formally state relative priorities or mention a process for setting priorities across projects.

Selection of priorities within the Program, however, are clearly described in various documents produced for the Health Protection Branch Program Review. The Responsibility Centre Profile document [Health Canada (undated)] produced for this Review by the Research and Standards Division of RPB (now the Consumer and Clinical Radiation Hazards Division) describes the following criteria in the selection of priorities for project areas:

- Health Protection Branch Risk Management Strategies and cost/benefit considerations, including hazard levels, populations at risk, public perception, ownership of responsibility;
- management feedback to yearly project area reviews;
- policy decisions by higher management.

All principles of the framework were used in the selection of the major health priority issues faced by the Health Protection Branch [Health Canada (October 1, 1993)]. Forty-nine priority health issues were identified using risk assessment, risk perception and risk management as components of the procedure to identify these priority health issues. Eight of these health issues were relevant to the Environmental Health Program evaluation.

PED's document review found that the framework concepts of risk assessment, risk perception and risk management were used, not only in the selection of priorities by the Directorate, but also by the Branch as a whole during the Program Review. However, the priority-setting process used in Program Review appears to be a one-time exercise; there is no indication such Branch- or Program-wide setting of priorities is done or will be done on a regular basis.

1.3 CLIENT/STAKEHOLDER INVOLVEMENT IN RISK MANAGEMENT

1.3.1 PED Interview with Health Canada Officials

All Program officials interviewed were of the opinion that there has to be client/stakeholder involvement in the selection of priorities of the Program/Directorate. Some of the BCH Programs have already initiated consultations with client/stakeholders in the form of meetings, asking clients about gaps and improvements to the Program. Such meetings had been very useful to the Bureau, and BCH is planning to continue having such meetings every two to three years. Interviewees noted, however, that client/stakeholder involvement in selecting priorities can inject political pressures into the process. This could result in issues not based on much scientific evidence being given undue priority because of inaccurate public perceptions of them.

1.3.2 PED's Document Review

Risk perception and client/stakeholder involvement are in principle part of the risk management framework. Holliday and Associates note in their CEPA case study that stakeholders were not involved in the PSL I process, to avoid missing the tight deadlines under which BCH was working. One assumes that in the control option process this lack of involvement will have to be rectified, requiring some public education that might not have been needed if there had been earlier public consultations. This will especially become important in those cases where the most effective control option may be modifying public behaviour through education (p. 28-30).

Public consultations have already begun in preparing PSL II and in planning for the assessments of substances on that list. CEPA documents show early stakeholder involvement for the PSL II selection process [(Environment Canada and Health and Welfare Canada (April 1993)]. BCH and Environment Canada have proposed that PSL II will be screened by a panel of no more than 20 people (a proposed Ministers' Expert Advisory Panel). Members of this panel must have appropriate scientific background and experience in interpreting technical data and "be committed to the goals of the PSL process." Members will be selected by the Ministers of Health Canada and Environment Canada, after receipt of nominations. The goal of this panel is to identify potentially hazardous substances not already on PSL I and currently in the Canadian marketplace or resulting from commercial or government activity in Canada; the list can include individual chemicals or complex mixtures originating from identifiable locations or industrial sources. The intent is that PSL II should have no more than 30 substances on it.

Comments from stakeholders who reviewed the initial PSL II consultation document [Environment Canada and Health and Welfare Canada (May 1994)] generally addressed the use and adequacy of the proposed scientific criteria, some of which were modified by the Departments in the response. Comments also addressed the operation of the proposed Expert Advisory Panel, which comments will be referred to the Ministers and the Panel once chosen. The response document published by the two Departments called for substance nominations.

Also, several documents under GLHEP show continuous involvement of clients and stakeholders [Great Lakes United (August 20, 1990)],[Great Lakes United (September 1991)],[Toronto, City of (October 1992)]. However, documents from other areas of BCH and RPB do not show evidence of client/stakeholder involvement in the planning of program activities.

1.3.3 Other stakeholder consultations

There is a wide range of stakeholders with whom BCH arguably should consult in planning and risk assessment. Within the Department, these include LCDC, Food Directorate, and Health Promotion Directorate.

Outside the Department, there are many stakeholders who might profitably be consulted. These include other federal departments such as Environment Canada, Natural Resources Canada, National Research Council, and Canada Mortgage and Housing Corporation. Various non-governmental organizations could be consulted, as well as industry associations such as the Canadian Petroleum Products Institute, Canadian Water and Waste Water Association, Canadian Quality Association.

The mechanisms for consultation with stakeholders are varied. Some stakeholders are involved in bilateral discussions with the Program; Environment Canada is the primary example of this under CEPA. There have been multi-stakeholder consultations, such as those with the pulp-and-paper industry in Vancouver over pentachlorophenol.

There are also regular consultations with various Federal/Provincial Committees. For example, in the area of drinking water safety, the program will develop uniform risk assessment information on hazards and exposure, with the provinces providing some of the exposure data. Provinces, which directly regulate most drinking water in Canada, can decide on their own whether to adopt BCH's proposed drinking water safety guidelines; Alberta, B.C., Ontario and Quebec have adopted these Guidelines into their Drinking Water regulations.

Various programs and divisions within BCH have or are developing formal processes involving external stakeholders in multi-year project planning and priority-setting meetings. This occurs with drinking water guidelines, with the planning and priorities for the Great Lakes Health Effects Program, in air health effects, and under CEPA. BCH has involved a few external stakeholders in the past in their annual Project Area Review planning process, and there are plans to formalize external involvement in the PAR process.

There does not appear to be any overall plan for consultations with external stakeholders in EHP priorities, planning and risk assessment, beyond the project-specific processes. Arguably the legislation and organizational environments are sufficiently different among the various projects to render any consultative "master plan" unworkable or counterproductive. Program officials note that consultations can be time- and staff-intensive, as well as financially costly. There may be economies to be achieved by consolidating some consultations, but program officials seem to be sensitive to this and are looking to improve specific mechanisms. The evaluation team and our consultants did not uncover any external stakeholder complaints over a lack of consultation by EHP.

1.4 CONTRIBUTION OF THE FRAMEWORK TO THE COHERENCE, EFFECTIVENESS AND EFFICIENCY OF THE PROGRAM

The framework has not only contributed to the coherence, effectiveness and efficiency of the Program and the Directorate, but it has also provided a common basis on which the different program Directorates in the Branch may evaluate risk, thereby ensuring consistency in decision making. As mentioned above, the framework has been developed in the last decade under the leadership of the Environmental Health Directorate. The framework's risk assessment and risk management techniques were fully applied by the Bureau of Chemical Hazards using Formaldehyde and Vinyl Chloride as case studies [Health and Welfare Canada (January 1991b)]. The risk communication practices of the Directorate and the Branch were also examined using the framework [Leiss, William (1989)]. Most recently a Handbook in risk Communication has been published ([Health Canada (March 1994)]. Also the Directorate and the Branch's recent Program Review exercise applied the framework [Health Canada (October 1, 1993)].

Most program officials told PED the framework has made a major contribution to the functioning of the program and the way staff plan their work. One official summarized the views they all expressed, as follows:

> "The framework offers a lot to the Bureaux, it is a complete framework, it has regulatory options, non-regulatory options of an economic, advisory technological nature. It discusses methodologies for choosing between those options. It brings together risk perception and risk communication; it is all there. Just having the framework as background guidance within which to structure your thinking on how to implement a practical solution to a problem, is a big benefit. For example, within the Bureaux the framework permits anyone to visualize where they fit into the process, and where their impact is".

1.5 IMPROVEMENTS OR MODIFICATIONS NEEDED TO IMPLEMENT THE FRAMEWORK

Program officials commented that EHD's PARs are missing a feedback mechanism, and this should be part of this annual planning process. Although not something inherent in the framework, indicators of projects' success in meeting objectives should be added to the PAR process. Officials also suggested that long-range planning of human resources should be tied in with the different phases of the framework.

Planning can always be improved. However, there is an opportunity for some realignment and updating of the planning structure. There needs to be a more national focus but with regional input and involvement under the new HPB structure. There needs to be consultation without tying up all staff and preventing the work from being done; there may be more efficient ways of consulting, e.g. through advisory committees.

The linkages between the framework and the Directorate's planning process is not that obvious to all EHD staff. Some Program officials said that they do not perceive enough correlation between the risk management framework and EHD's planning process. Others are not aware of any linkages between the framework and the Project Areas Reviews.

1.6 CONCLUSIONS

Since 1984 the concepts of risk assessment and risk management have been introduced and form part of not only the Environmental Health Directorate and the Environmental Hazards Program but they have also expanded to the Branch level, under EHD's leadership.

The framework is frequently used in the planning and operation of the Program. The yearly Project Area Reviews which BCH uses to plan its work make reference to the risk assessment and risk management framework. The logic charts used in the 1994/95 PARs clearly show the linkages of Program objectives and outcomes to that of risk assessment and management. Under the CEPA PSL I Assessments, BCH has widely used the framework, particularly in hazard identification and risk estimation of chemical substances. Risk management and hazard identification are frequently used in the GLHEP activities.

There is a perception among program officials that the framework is not formally used in the priority setting of the Directorate's annual Projects Area Reviews. In the case of CEPA, the setting of priority substances is within CEPA and not in the framework. However, various EHD/HPB documents show that the framework has been used in the selection of priorities. Planning documents from the Radiation Protection Bureau show that planning of priorities are based in the risk assessment and risk management concepts of the framework. In a 1991 planning document [Health and Welfare Canada (November 5, 1991)], RPB proposed a two-phase evaluation procedure for prioritization of non-ionizing radiation emitting devices, the same two-phase evaluation procedure is used for radiation emitting devices. The framework was also used extensively in the Branch's Program Review exercise [Health Canada (October 1, 1993)]. Forty-nine health-priority issues were identified for the Health Protection Branch using risk assessment, risk perception and risk management as components of the procedure to identify these priority health issues.

The framework has contributed to the coherence, effectiveness and efficiency not only of the Program but also of the Branch. It has provided a background and flexible guidance within which to structure EHD/HPB thinking. EHD's Bureaux use the same planning process. EHD has a one week planning review where all Bureaux go through all the projects using the same procedure. As mentioned above, in 1993 the framework was used in the Branch's Program Review for the identification of the 49 HPB's health priority issues. The framework is also used in risk communication; just recently the Branch and the Directorate have prepared a Health Risk Communication Handbook [Health Canada (March 1994)].

The framework has been evolving through time. To continue implementing the framework effectively in the planning of the operations of EHD and the Program, the following is needed:

- client/stakeholder involvement in the selection of priorities of the program;

- a formal process to select priorities in the PAR reports;

- participation of all Divisions in the selection of priorities of Project Areas and more use of the framework in the selection of priorities;
- more use of the framework in planning the Program's and Directorate's activities, including those of communication;
- relating long range planning of human resources and commitment of financial resources to the framework; and
- implementation of a formal feedback mechanism in the PARs.

2. PROGRAM COORDINATION WITH OTHER PROGRAMS, CLIENTS AND STAKEHOLDERS

2.1 COORDINATION OF EHP ACTIVITIES

The EHP uses both formal and informal coordination mechanisms. Formal (pre-arranged) coordination mechanisms take the form of committees, Memorandums of Understanding, written agreements, working groups and program workshops. Informal coordination mechanisms use ad hoc telephone conversations, written correspondence and meetings.

There are eleven federal departments that interact with the EHP regarding CEPA (see Box 2). However, both Environment Canada (EC) and Health Canada (HC) are responsible for CEPA. Health Canada is responsible for the health aspects of the Act while Environment Canada is responsible for aspects regarding harm to the environment and the administration of the Act. [8] As a result, this evaluation will focus on the coordination mechanisms between EHP and EC.

1. Agriculture and Agri-Food Canada
2. Environment Canada
3. Fisheries and Oceans
4. Foreign Affairs and International Trade
5. Indian and Northern Affairs Canada
6. Industry Canada
7. Human Resources Development Canada
8. National Defense
9. National Research Council
10. Natural Resources Canada

2 Other Federal Departments that Interact with EHD on CEPA

The coordination mechanisms between Health Canada and Environment Canada for CEPA are essentially formal in nature. These include a CEPA management committee and subcommittees. These mechanisms are described as adequate by those interviewed by Program

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[8] John Park, Michael Holliday and Catherine Vardy,1995, p. 8

Evaluation Division (PED). An example of the effectiveness of these mechanisms is seen in the air quality program. Environment Canada and Health Canada both work in the area of air quality. They have organized joint meetings to discuss program issues and directions. For example, at a meeting in September 1993, the two departments specifically addressed the issue of opportunities to enhance the integration of their air-health-effects objectives and activities. This meeting acknowledged the existence and importance of both formal and informal coordination mechanisms and identified areas needing improvement. (Nina Arron and Michael McCulloch, 1993)

The main concern that surfaced during this part of the evaluation was the abundance of committees. "Frequent comment was made of the large number of such committees and the demands placed on time. Many state that ad hoc dealings or communications (just picking up the phone) are best, especially when time constraints and urgent issues must be confronted."[9] In addition, EHD's DG belongs to about 116 committees, most of them interdepartmental and not of EHD's own making (see p. 23 for a sample of these committees). The DG cannot possibly attend all these meetings, and he often delegates someone else to go. PED is struck by the large number of committees and the workload and time it takes merely to attend the meetings and read the agendas and attachments. PED was told that until several years ago it required a cabinet submission to establish an interdepartmental committee; committees were made of senior officials, who usually attended. PED was told that now Departments can form interdepartmental committees without central agency approval. While senior officials (such as Assistant Deputy Ministers or Directors General) are often nominal members, frequently there are meetings at which everyone present is a delegate rather that the nominal member. Program officials wonder whether all these committees are necessary and a productive use of staff time.

> However, the importance of formal coordination mechanisms cannot be forgotten. The experiences of EHP relying solely on informal mechanisms have not always been successful. From our interviews with Health Canada staff, it appears there is some scope for more systematic and regulation consultations between the EHP and other parts of Health Canada. Health Promotion Directorate has good, regular links with the Great Lakes Health Effects Program, but interviewees suggested there is scope for more systematic and regular consultations on BCH's overall planning with both LCDC (on research priorities and design) and Health Promotion Directorate (on public communications strategies for research findings).
>
> EHD often undertakes projects in conjunction with the Laboratory Centre for Disease Control (LCDC). In cases where there are no formal coordination mechanisms the two directorates rely on interpersonal relationships. When these relationships are good,

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[9] RFI and ARA Consulting Group Inc, 1995, p. 6.

> effective coordination takes place. However, when these relationships breakdown, there is no formal tie to keep the two directorates working together.
>
> An example of what some Health Canada officials viewed as a failure of informal mechanisms is demonstrated by an asthma study performed by both the LCDC and EHD. LCDC developed a database on asthma and hospital admissions. This database was given to the EHD with the understanding that EHD would provide air pollution data in exchange. PED was told the exchange never took place and the LCDC did not see the results of the asthma study until its final stages.

Other Federal Agencies that EHD deals with include the Atomic Energy Control Board (AECB), the Federal Environmental Assessment Review Office and the Medical Research Council of Canada. This evaluation looks at the coordination mechanisms between Health Canada (in particular, the Radiation Protection Branch, [RPB]) and AECB under the RED Act.

Essentially, the only formal coordination mechanism that was identified in the evaluation, between AECB and RPB was a Memorandum of Understanding dating back to 1981, between AECB and the Department of National Health and Welfare. This memorandum contains an agreement to continue consulting each other with respect to the licensing of particle accelerators.[10] However, there is a large amount of informal co-ordination between the clinical medical physicists working in therapeutic radiology in Canada and RPB, AECB and physicists at Theratronics. This mechanism was said to work very well. [11] In addition, since the abolishment of the RPB Federal/Provincial Committee on Radiation Surveillance, RPB participates in a similar committee held by AECB. Overall, interviewed Health Canada officials agreed that RPB has established good coordination mechanisms with the AECB.

The coordination mechanisms between the provinces and EHP are described as very good. Specifically, "Federal and provincial government 'colleagues' working in close proximity to EHP, have the perception of very good or improved working relationships and of the effective coordination of initiatives.[12]

An example of effective provincial coordination mechanisms is the Federal/Provincial Subcommittee on Drinking Water. At the October, 1994 meeting between the provinces, territories, Health Canada and Environment Canada, there was the opportunity for the provinces to raise concerns regarding inconsistencies in the protocol for boil water orders. This alerted the Federal authorities to a possible need for a standard protocol. This meeting also provided an opportunity for these groups to coordinate their actions to produce a Bacteriological Criteria Document.[13]

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[10] Alfred Gunter and Michael Holliday, 1995, p. 13

[11] Ibid., p. 31.

[12] RFI and ARA Consulting Group Inc., 1995, p. 7.

The mechanisms to ensure overall cost effectiveness are adequate. An example would be the Air Quality Program, Issues and Directions meeting held in September 1993. This meeting specifically looked at the opportunities to enhance cooperation and the sharing of staff as a means of being cost effective.[14]

The mechanisms to identify gaps in mandates are adequate. An example is visible with the Air Quality Program. From their Issues and Directions meeting held in September 1993, it was identified that no mandate exists for indoor air.[15]

Overall, the mechanisms to avoid overlaps and duplication are adequate. Overlaps and duplication were not a major issue cited in interviews concerning the EHP, given the highly specialized and (in Canada) unique expertise the program has in many areas.

Committee meetings, such as that for the Air Quality Program, held in September 1993, adequately identify areas of duplication and propose strategies to eliminate them. These strategies take the form of more joint planning, dedication of staff and resources towards organization and the involvement of scientists and staff earlier in the planning processes.[16]

Several ways to improve the coordination of EHP activities were suggested during interviews with EHD and Health Canada officials, or determined from the review of relevant documents.

- Reduce the number of committees.
- Devise a system to set priorities.
- Have a more phased planning approach which brings players in to the planning process earlier.
- Establish an Internet Connection.

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[13] D. Rocan [chair], 1994.

[14] Nina Arron and Michael McCulloch, 1993.

[15] Ibid.

[16] Ibid.

- Design a national standard for data collection so that data gathered by one group can be utilized by many groups.

- Make use of newsletters and brown bag lunches to encourage the sharing of information.

- Make use of electronic bulletin boards.

2.2 COORDINATION OF EXTRAMURAL RESEARCH

The Hall Panel (the Ministers' Priority Substances Advisory Panel for PSL I) recommended "research to address the identified gaps (in supporting the assessment process) should receive priority funding. Where research is needed, innovative mechanisms for funding should be investigated, e.g. matching funding arrangements between public and private sectors." (Consultation Document A, pp. 13-14) One would think that an appropriate mechanism would be to use various federal extramural research programs, which are intended at least partially to help provide evidence to support Departmental program and policy decisions. One would also hope there could be coordination of research efforts into environmental health hazards across the federal government, the provinces, and the private sector.

The use of such mechanisms has not been as effective as it might be. For example, the *Evaluation of the Canadian Environmental Protection Act (CEPA): Final Report* (Evaluation Branch, Environment Canada, December 1993) found the following:

> "PSL assessments rely primarily on existing information. The efficiency of the assessment process depends largely on the efficiency with which existing information can be accessed. This requires arrangements to collect the disparate information throughout the federal government, from other governments, from academia, and from the private sector. Such a requirement is an ongoing challenge." (p. 56)
>
> "There is little coordination between the related science efforts across government, between the federal and provincial governments and with the private sector." (p 2)
>
> "Many of those we interviewed argue that the scientific efforts of, for example, Fisheries and Oceans, Agriculture Canada (pesticides), Workplace Health and Safety (Health Canada) and Human Health (Health Canada) remain on separate tracks." (p 54) The report states that the fragmented, media-specific approach can lead to serious problems such as transferring pollutants from one medium to another, errors in estimating the impacts of toxic chemicals on receptors, and lack of interdepartmental coordination of control mechanisms (pp. 54-55).

> "Although both (Environment Canada and Health Canada) have staff who act as reviewers for the National Science and Engineering Research Council and for the Medical Research Council, both councils have declined requests for support on the grounds that the (CEPA) assessment work is not sufficiently 'cutting edge.'" (p. 58)

Program officials report mixed experiences with Health Canada funding programs, such as NHRDP (National Health Research and Development Program), and other funding programs such as those of the Medical Research Council (MRC). Program officials recognize research funding by such agencies as MRC is intended to support basic research, but they note NHRDP is supposed to be directed to supporting Health Canada's needs. There are always competing priorities for limited funds, and EHD's input has been sought on specific proposals related to the EHP. Senior program officials do have regular contact through the advisory committee for the NHRDP. However, officials throughout EHD (including those who sit on the advisory committee) expressed puzzlement at how NHRDP funding priorities are set.

NHRDP does have an environmental element. After completing the PSL I assessments, Environmental Substances Division of BCH developed a paper identifying all the important research needs identified in the PSL process ("A Summary of Health-Related Information Gaps and Research Needs: Priority Substances List," Environmental Substances Division, BCH, EHD, 5 July 1994). Copies of this paper were provided to NHRDP and to the Canadian Centre for Toxicology. It is too early to say whether this paper will influence research priorities in those agencies.

When BCH officials did the research for the publication "A Vital Link: Health and the Environment in Canada," they reviewed more than 10 years of NHRDP research reports. They found very little information in those ten years of reports they could use for the publication or to help them assess environmental health risks. They found the NHRDP research largely an academic approach to science and risk assessment: it was impractical for a government regulatory program.

Each year the BCH receives is asked to review a number of NHRDP proposals. Program officials recognize NHRDP must balance the opinions of many reviewers besides those in the EHP, but many program officials feel current mechanisms for providing input do not support a strong role for BCH in the priorities and operation of NHRDP. For example, one EHP official told us a proposal that his staff reviewed several years ago would have been particularly useful to his division. It dealt with the interaction of solvents and toxic responsiveness. His staff rated it highly; it was proposed by a group of researchers at a major Canadian university who had a long-standing record of good work in this area. The research would have helped his Division in risk assessment. In spite of the favourable rating, the proposal was not funded. This was frustrating for this division, because the staff had worked quite hard at reviewing this and other research proposals. The official felt NHRDP staff did not give his division's comments much weight in the decision-making. The official is accordingly sceptical about NHRDP being able to accommodate the program's research needs.

The MRC tends to be very medically oriented, focusing on the treatment of disease. Thus its research has limited applicability to the EHP. However, the MRC was involved with EHD in the bio-technology area in helping them to produce guidelines.

There are some successful EHD partnerships with research agencies. One is the St. Lawrence Health Effects project, which has established good links between NHRDP, the BioRegional Health Effects Division, the FSLQ (Quebec's counterpart to NHRDP) and several Quebec universities. BioRegional Health Effects Division are pleased with the cooperation and funding these bodies, including NHRDP, have contributed to their research needs. One limitation the Division has found in dealing with NHRDP is that it can get input into granting decisions only if the Division has money to contribute to the process. The Great Lakes Health Effects Program has only operating dollars, however, while NHRDP has grants and contribution funds. There are financial constraints on using operating dollars for contribution programs, which limit the amount of joint effort that is possible.

Another success story for EHD is the Eco-Research Program, where EHD is indirectly involved. The interdisciplinary program is a tripartite effort involving MRC, NSERC (Natural Sciences & Engineering Research Council), and SSHRC (Social Sciences & Humanities Research Council). EHD is a member of the program's Peer Review Committee and feels it has meaningful input into that program's funding priorities and decisions.

2.3 CONTINUITY OF PROGRAM RESOURCING

Toxicological and particularly exposure studies in environmental health have long gestation periods. As one EHP official put it, "in risk assessment and risk management we must think very long term." While some EHP officials are very concerned about the adequacy of program resource levels to meet program targets within deadlines set for them, others told us EHD's resources are adequate to the task if EHD could set its priorities and have a guarantee that its resources, at whatever defined level, will remain stable for a period of some years, so the long-term projects they must undertake can be completed. The research work on many projects or for many environmental hazards cannot be completed in one or two years; research is complex and expensive, and the health effects themselves can have gestation periods extending over decades. "Fixing" environmental hazards cannot be done quickly either; a good example is ozone-depleting substances, whose effects in the upper atmosphere will continue for decades, even if emissions were permanently turned off world-wide, overnight.

It is very difficult to plan and carry out research and community action projects on environmental hazards if funding is sporadically turned on and off "like a tap" with resource cuts, program reviews, and threats of the same. As one program manager told us, "cut my programs in half if you must, but then at least guarantee consistent funding for the remaining half, if you are serious about this program."

Long work hours under demanding time pressures, coupled with funding, staffing and organizational uncertainty, have left some of the program's professionals feeling "burned out," discouraged, and actively considering career or employment changes. An undercurrent of concern in most of our interviews, both in BCH and RPB, was the impact of working and funding conditions over the past several years on the Program's most important resource, its staff. Interviewees and interviewers alike recognize these conditions and reactions are not unique to the Environmental Hazards Program, but this makes them no less valid a concern.

A related concern centres on succession planning for expert staff. As one senior manager told us, "my staff in this area are mono-molecular thin; ... what happens to (a particular program) if (a particular expert) gets hit by a bus tomorrow?" Many expert professionals in the very specialized and somewhat esoteric fields needed for the EHP are approaching retirement age. In some of the science disciplines represented in the program it can take years to develop and nurture the necessary expertise and to provide the necessary collegial support, backup and succession planning. This is very challenging under the current fiscal and staffing realities.

EHD sometimes can leverage inexpensive but priceless help from experts in the universities or in other countries, through personal networks and connections of their research scientists. To maintain these networks requires a certain amount of conference travel. EHD is a multidisciplinary organization with a spectrum of a few experts in many disciplines; its unique strength is its ability to integrate information from many science and medical disciplines into an informed judgment on risk and on risk management.

It is very important to protect the stability of funding levels for priority long-term research projects in environmental health. Such projects cannot be effectively or efficiently carried out if research staff are uncertain from one month to the next whether their funding will continue, whether they will have jobs, or whether research partners in communities, universities or other governments can count on continued support. Once such projects have begun, cutting budgets beyond critical levels or shutting down programs before they have been able to show results represents a waste a public money. It would be better to fund fewer such projects, but to guarantee the funding levels for them for the expected duration of the project, than to fund many projects and submit many or all to on-going budget and staff cuts to meet deficit reduction targets. Arguably it would be better never to undertake such projects in the first place, if funding levels cannot be guaranteed. *PED encourages EHP to identify those research projects and programs that require long-term assured funding to be effective and to seek whatever formal* *agreements or assurances it can secure from the Deputy Minister or the appropriate delegated financial decision makers who could effect these.* It is important to have better coordination of federal research efforts in the environmental health area and more input from the EHP into the Department's directed research programs, such as NHRDP.

CHAPTER SIX: PROGRAM EFFECTIVENESS

1. DEVELOPING AND REPORTING INDICATORS OF PROGRAM EFFECTIVENESS

There is a spectrum of health and environment indicators one can contemplate developing for the Environmental Hazards Program, at least in theory. The spectrum of indicators spans the range of outputs, expected results, and the ultimate objective shown in the logic chart for the program (see Figure 3 of Chapter Two of this report).

One can relatively easily develop indicators of the quantity, quality and impact of products and other outputs of the Program, such as scientific reports and publications, conference proceedings, and advice given to clients or stakeholders. One can with a bit more difficulty identify indicators of the links between these immediate program outputs and such results as changes in the behaviour or awareness of clients and stakeholders regarding the management of environmental health risks. There are measurements and indicators of the presence and levels of environmental contaminants and health risks in the environmental and in the human body. One can attempt to detect links between exposure to environmental contaminants and program outputs (working in one direction in the program's logic chart) and ultimate health effects such as mortality and morbidity (working in the other direction in the program's logic chart).

Given the variety of health risks that the Program addresses, the variety of health effects these risks can have on humans, and the variety of activities in which the Program engages to address the health risks, it is not possible to develop a single indicator of program success. Rather, one must work with the full spectrum of indicators to illustrate and monitor the direct and indirect contributions the Program makes to the health of Canadians.

The exercise is further complicated by uncertainties in attribution of cause and effect of some of the linkages that one assumes exists between program activities, program products and outputs, immediate effects, and ultimate health effects. These uncertainties arise because of compounding variables at all levels in the causal chain, such as the activities and outputs of programs by other departments and governments and non-environmental health risk factors that can produce the health effects being monitored. There are also limitations on the magnitude and quality of data needed to demonstrate certain links between health and the environment. As RFI noted in its report to us, "most interviewees felt that it is extremely difficult (some feel impossible) to derive indicators of ... a reduction in human mortality and morbidity as a result of program activities. In the words of one individual, you will 'tie yourself in knots trying to do it.'"[17] Yet, in times of shrinking budgets and competing demands for scarce resources, it is necessary to develop, monitor and report such indicators as are feasible.

One example of problems in measuring health effects from environmental contaminants comes from the Great Lakes Health Effects Program. A draft report program officials copied to us on a survey of Ontario residents concerning sport fishing says the following:

> "The results of this study raise questions around the cost effectiveness of conducting Canadian epidemiological investigations into the possible human adverse health outcomes, particularly reproductive outcomes, in the Great Lakes Basin. Specifically: there are relatively few people who consume sport-caught fish and wildlife in any quantity, there is no easy or economical way to locate these people and most of the adverse health outcomes are relatively uncommon. *Since true relative risks of water-borne and outdoor air pollutants net of all other potentially confounding risk factors are likely to be very low*, demonstrating a significant effect at what is essentially the limits of detection would require a multi-million dollar study involving most of the Ontario population."[18]

Indicators are for different uses; ideally, the same indicators can serve multiple uses.

> Program managers need indicators to provide guidance on how to adjust the program to achieve specific objectives.
>
> Evaluators and senior officials need indicators of program results to help make resourcing decisions among competing programs and program activities.
>
> Politicians and the public want evidence that important environmentally-related health problems are being addressed and that public money is being spent wisely and effectively.

Officials throughout both Bureaux of EHD are aware of the importance of developing a range of indicators of their program's direct and indirect effects and benefits. This was a recurring theme in all our interviews with them. Another indicator of their interest in the topic is the interest and participation in the indicators workshop RFI conducted for PED as part of the evaluation; participation extended from the Director General down the organization chart to research scientists from various parts of the Directorate. The following paragraphs summarize the major ideas that were expressed in the interviews and the workshop.

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[17] RFI, op. cit., p. 14.

[18] "Ontario Cohort Study: Report on the Great Lakes Basin Anglers Survey," Great Lakes Health Effects Program, June 1994 Draft, page ii.

The best Health Canada can do in finding indicators of the effectiveness of the EHP is to look for evidence of the program's contribution to a reduction in the exposure of Canadians to environmental hazards. One must make a "leap of faith," albeit a reasonable one, that a reduction in exposure will translate ultimately into health benefits for Canadians. Direct demonstration of those health benefits would be difficult or impossible and would take decades to show up in mortality and morbidity statistics.

> Many health effects resulting from exposure to environmental contaminants, notably carcinogens, do not show in the human body until years or even decades after the exposure to the contaminant. Many health effects linked to environmental contaminants are also linked with non-environmental factors that can be hard to measure and control in epidemiological studies. Park, Holliday and Vardy note that for some chemical hazards, the uncertainties surrounding the estimates of TDI can be several orders of magnitude, rendering precise benefit-cost analyses of control options potentially very unstable. They also note the level of environmental contaminants in Canada are generally low (especially compared with eastern Europe), the incidence of environmental illnesses are also low, and therefore it can be hard to draw links between individual contaminant levels and human health.[19] There are a few exceptions, however; the air health-effects program in BCH has done pioneering research showing a direct link between levels of air pollution in Ontario communities and hospital admissions for respiratory problems in those same communities.

Demonstrating a direct causal relationship between delayed health effects and most of the operations of the Environmental Hazards program (or the operations of any other environmental program of any government) is thereby rendered virtually impossible, certainly within the lifetime of most programs and governments.

Balancing the cost of the EHP against direct or indirect health benefits is a problematic calculation in these circumstances. Even if the health effects could be readily and unambiguously quantified and attributed to the program, there remain difficult value judgments about the relative importance to be given, for example, between "a substance which has the potential to mildly irritate a significant proportion of the population (but otherwise has no foreseeable health effect) ... (and) one that has the potential to cause, say, one premature death in 1,000,000 after a lifetime of exposure?"[20]

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[19] Park, Holliday and Vardy, op. cit., p. 43.

These are not questions of merely academic or philosophical importance; with governments facing severe deficit-reduction pressures, programs such as EHP face increasing competition from other health-related programs for shrinking budgets. Though scientifically defensible measurements and computational algorithms to support cost-benefit comparisons among such programs do not seem to exist, decisions implying such comparisons and trade-offs are going to be made. As an alternative to the rigorous proof that does not and may never exist, decision makers need to be given and to consider the best available indicators of the severity of health problems the program addresses, the value the program adds to reducing or solving these problems, and the costs entailed. As the RFI report notes,

> "*Inference* will eventually play a part in assessing program impact. Qualitative measurements of program outputs and expected results do not provide conclusive evidence of the program's impact upon its ultimate objective. It is at this point that a leap of faith is required, and that the ultimate impacts be inferred based on the information at hand. The willingness to make this inference will be a function of how well indicator users (decision-makers) have been communicated with and 'sold on the idea' of the rationale for the indicators in question."[21]

These concerns about the feasibility of measuring direct program impacts on health mirror the conclusions Environment Canada reached in its evaluation of CEPA.

> "It is difficult to determine the direct environmental and health impacts of CEPA for three reasons. First, it is too early to tell what impact CEPA is having on environmental quality and human health; relatively few regulations have been developed and only a relatively short time has passed during which these regulations could be expected to produce tangible effects. Second, it is difficult to separate the effects of actions taken under CEPA from other factors, such as provincial actions, green consumerism, industrial changes due to the recession, free trade and technical advances. Third, data and knowledge related to health and environmental conditions, toxic levels, and cause

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[20] Holliday, Michael G., and John Park (January 1995). *Musings on Health and Environment Indicators*. Discussion paper prepared under contract with Program Evaluation Division, Health Canada, page 7 (appended to RFI report).

[21] RFI, op. cit., p. 37.

> and effect relationships are limited. There are many data gaps, and the understanding of impacts is particularly weak at the ecosystem level."[22]
>
> "... indirect effects may be more important than any direct effects. It is virtually impossible to attribute these indirect health and environmental impacts exclusively to CEPA as many other factors are involved. All that can reasonably be asked is whether CEPA's indirect effects are moving action in the right direction - are they supporting or undermining overall efforts to improve health and environmental conditions?"[23]
>
> "Our discussions with Health Canada reveal that no monitoring activities to determine the broad health impacts of CEPA are ongoing or planned by the Department. Scientists at Health Canada believe it is impossible, in most cases, to link environmental effects directly to health effects."[24]

Participants in the indicators workshop conducted for PED by RFI suggested that indicators be chosen to meet the following criteria:

- relevant to determining whether program objectives are being met
- current (timely, based on up to date information)
- able to provide early warning of problems and to identify gaps
- simple to communicate and understand
- credible
- consistent

It is important to establish and maintain baseline data on indicators, perhaps for decades, if one wishes to monitor and demonstrate trends in indicators. For example, Holliday and Park note that "cadmium has a very long biological half-life in humans (about 30 years) and it would therefore be necessary (to track cadmium exposure) not only to obtain baseline data of renal cadmium levels in the Canadian population but also to ensure that monitoring of these tissue levels was carried out for several decades after controls were instituted."[25]

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[22] Environment Canada, Evaluation Branch. *Evaluation of the Canadian Environmental Protection Act (CEPA): Final Report.* Prepared for the Evaluation Branch, Environment Canada, by Resources Futures International, December 1993, page 128.

[23] Ibid., page 131.

[24] Ibid., page 135.

- feasible to obtain, in time and cost, i.e.,

  (1) incorporate within ongoing monitoring of programs

  (2) long-term commitment needed to consistent measurement

  (3) the cost of generating indicators should not be at the expense of the program itself and should not to take resources away from essential program activities.

Various indicators of exposure reduction were suggested to the study team. The following paragraphs summarize some of the more promising indicators, listed in declining order of proximity to ultimate health effects.

1. Direct indicators of health and environment links. Notwithstanding the limitations cited above, Departmental officials offered PED several promising suggestions concerning indicators of health effects.

   Generally, it will take decades for environmental health risks to show up in mortality or morbidity statistics. However, LCDC has advised RPB that it is likely the effects of the UV program on malignant melanomas may show up sooner than with other environmental health programs. If persons exposed to solar UV in their childhood develop malignant melanomas as a result, this often shows up in their twenties. This suggests that within 10-15 years of the onset of the solar UV program, there may be a detectable effect in mortality and morbidity statistics. Also, reproductive health effects have a short latency and may be more likely as a source of indicators of environmental impacts than other effects having a long latency period.

   The degree of exposure and the relative degree of contamination should also be combined as one indicator. A community or region could be contaminated, but if only three people reside in the area, the overall risk to health is modest. In contrast, a greater risk to health could result from lower levels of contamination occurring in an area populated by 100,000 residents. In effect, one needs a population attributable risk measure - the number of people affected multiplied by the risk level. Expenditures allocated to cleaning the environment should be focused on regions where the 'health - environment' index is the highest. Indicators need to be region specific; developing indicators for the whole country is unwarranted because they are too general. Region-specific measures will also help provincial and local authorities to improve their environmental planning activities.

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[25] Holliday and Park, op. cit., p. 12.

2. Direct measurement of exposure to contaminants

   - Measurement of contaminant levels in the body, e.g. through tissue samples.

   - Measurement of contaminant levels in food crops, fish and game.

   - Measurement of contaminant levels in the environment, including number of times in a fixed period accepted standards or guidelines for contamination levels are exceeded

3. Indirect measures of exposure reduction through risk management by individuals, organizations, and governments

   - Adoption of and compliance with the EHP's exposure guidelines by government departments and other organizations that have direct or regulatory control over emission levels.

   - Awareness and use of the EHP's guidelines on risk management, e.g., the awareness and use of WHIMIS information by industrial occupational safety and health committees, and the awareness and use of RPB guidelines by radiologists.

   - Self-reports of public behaviour changes in exposing themselves to and managing environmental health risks, e.g., survey responses to questions about the use of sunscreen and protective clothing to reduce exposure to solar ultraviolet radiation.

   - Market data on the sale of appropriate risk-management products, such as high-SPF sunscreens.

4. Increased public awareness (measured through opinion surveys) of environmental hazards and ways to reduce or manage exposure to them, assuming that people who are aware will engage in the appropriate behaviour.

   As one Departmental official said, one needs to have faith that the right information will influence the behaviour of Canadians so that they reduce their degree of exposure. Hopefully, this will eventually lead to reductions in morbidity and mortality. Given the objectives of the EHP, it makes sense to look at the success in modifying behaviour or awareness, as well as other indicators of the program's immediate outputs and their effects. If EHD gives advice, is it heeded? Is EHD seen by others as a reliable source of information on health effects from environmental risks?

5. Measures of the volume of communication to the public on risk management (e.g., copies of publications, minutes of air time).

6. Indicators of awareness of and support for EHP activities by direct clients and partners, as well as by stakeholders and the public.

 Such "political indicators" are controversial. Efforts by government officials to monitor (never mind influence) the "public profile" of their programs can be cynically interpreted as self-justifying and a waste of public funds that more profitably might be spent otherwise. As several program scientists commented in the indicators workshop, recipients of program advice and communications (even of the non-regulatory variety) do not always want to hear the advice the program is giving them. Some participants in the workshop felt that seeking evidence of client approval or satisfaction with program advice can be akin to evaluating the effectiveness of highway patrolmen by asking speeding violators how satisfied they are with their speeding tickets.

2. Health Risk Assessment Under CEPA

Environment Canada is responsible for the administration of the Canadian Environmental Protection Act (CEPA) and for administering and enforcing regulations or other mechanisms developed pursuant to that Act. Health Canada is responsible under the Act for formulating "objectives, guidelines and codes of practice with respect to the elements of the environment that may affect the life and health of the people of Canada" (CEPA, subsection 9.(1)). Under CEPA Health Canada shares with Environment Canada joint responsibility for compiling and amending a Priority Substances List (PSL), for collecting, evaluating, and publishing data and information on PSL substances, and for making "recommendations respecting measures to control the presence of the substance(s) in the environment (CEPA section 15)." These latter measures are sometimes referred to by EHP staff as "control options." All Health Canada responsibilities under CEPA are managed or coordinated by the Bureau of Chemical Hazards (BCH) in EHD.

The first PSL (PSL I) contained 44 substances, following a recommendation of 50 substances submitted to the Ministers of Health and Welfare and of the Environment by a multi-stakeholder

Priority Substances Advisory Panel (the "Hall Panel") established in 1988. The Ministers were required to publish Priority Substance List Assessment Reports (referred to herein as "CEPA assessments" or "assessment reports") for all 44 substances by February 1994. At the time of this writing, the two Departments are in the process of establishing a second Priority Substances List (PSL II), following a public consultative process (see for example "Consultation Document A" and "Consultation Document B").[26]

2.1 INFORMATION REQUIRED FOR CEPA ASSESSMENTS

Under section 11 of CEPA, a substance is "toxic" if it is entering or may enter the environment in a quantity or concentration or under conditions:

(a) having or that may have an immediate or long-term harmful effect on the environment;

(b) constituting or that may constitute a danger to the environment on which human life depends; or

(c) constituting or that may constitute a danger in Canada to human life or health.

The House of Commons Standing Committee's report provides a good, concise description of the CEPA risk assessment process. "For a substance to be classified as toxic under CEPA as it is currently written, there must be a possibility that the substance will *enter* the environment, that living organisms will be *exposed* to the substance, and that there will be an actual or probably *effect* resulting from that exposure. These three components of the definition of toxic are known as the '3 Es of CEPA toxic.'" CEPA assessments must demonstrate each of these three components. The third and final part of the risk assessment is the "effects assessment ... (the purpose of which is) to determine acceptable concentrations for (natural) populations, communities and ecosystems exposed to the substance in Canada and, second, to establish whether the acceptable concentrations are exceeded by prevailing levels in the environment." [27]

As part of an assessment under CEPA, scientists and evaluators need information on: (Consultation Document A)

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[26] "Preparing the Second Priority Substances List under the Canadian Environmental Protection Act (CEPA)": An Invitation to Stakeholders to Comment on the Federal Government Proposals for..." Environment Canada and Health Canada, April 1993 ("Consultation Document A"); "Response to Stakeholders' Comments on the Federal Government Proposals for Preparing the Second Priority Substances List under the Canadian Environmental Protection Act (CEPA)" , Environment Canada and Health Canada, May 1994 ("Consultation Document B")

[27] House of Commons Standing Committee on Environment and Sustainable Development, "It's About Our Health! Toward Pollution Prevention: CEPA Revisited," June 1995, pp. 61-2.

- the chemical and physical properties of the substance,
- the quantities manufactured, used and imported into Canada,
- the movement and persistence of the substance in the environment (exposure levels and routes),
- the effects of the substance on human health (toxicity),
- the effects of the substance on animals and plants (toxicity),
- the results of long-term and short-term exposure to the substance (toxicity),
- ability of humans and other organisms to metabolize the substance (exposure levels and routes), and
- levels the substance in the environment, including in biota, soil, sediment, water and air (exposure levels).

PSL I (Hall Panel - Ministers' Priority Substances Advisory Panel) recommended that

> "decisions as to whether a substance is toxic or capable of becoming toxic should be made expeditiously, using acceptable scientific techniques to estimate the probable risk whenever this is possible" . . . "Where the preponderance of data indicates that a problem exists ... the acquisition of a fully satisfactory data base may not be possible and action may be needed."[28]

Park *et. al.* observes that BCH made innovative use of modelling to circumvent data gaps, showing that monitoring data are not essential, as long as one has some physiochemical data and some basis for estimating releases into the environment.[29]

Even so, eleven of the forty-four substances on the PSL I list could not be assessed for lack of information. Program officials suggest the information gaps are likely to be more serious with any PSL II list to be developed. Many substances were placed on the PSL I list because much is known about them, and it was thought assessing them would be relatively easy. Most of the "easy" assessments of substances that are likely candidates for CEPA-toxicity have already been done. The consensus of the program officials whom we interviewed was the information gaps are likely to be worse with PSL II, especially for exposure and exposure routes.

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[28] "Consultation Document A," p. 13-14.

[29] Op. cit., p. 23.

Park et. al. (Holliday-CEPA case study) noted with respect to the information in the CEPA assessments they reviewed:

> "With some exceptions ... the information on 'traditional' toxicity was quite good. Exposure data, however, were often incomplete, both in terms of the environmental levels of pollutants and their origins. Some of this incompleteness may be due to the limited amount of effort devoted to investigating source/exposure level relationships, but the majority almost certainly reflects the difficulty of determining quantities of pollutants released into the environment and the behaviour, transport, and fate of the pollutants after they are released. In this context, we cannot resist throwing in the truism that given unlimited time, resources, and money anything is possible. And this raises the question as to the amount of effort society is prepared to devote to tackling such problems." (p 26)

2.1.1 Toxicity Information

All interviewees believe the Program has good information on the toxicology of PSL substances. Health Protection Branch has separate toxicology laboratories in Environmental Health Directorate, Food Directorate, and Drugs Directorate. These laboratories serve programs governed by different legislation and in some cases with different standards for what constitutes an acceptable health risk. Analytical methods, data, and analyses to serve the particular needs of one program are not always directly applicable or appropriate to the needs of another program.

It has been suggested it might be more efficient to consolidate these toxicology laboratories into a single centre. The officials PED interviewed for this evaluation expressed the opinion that it is better on balance to maintain separate laboratories. The focus of the work in these different laboratories is quite different. One EHP official noted there is a scientific richness in having three separate laboratories approaching toxicological investigations from different perspectives; each of these perspectives requires a critical mass of expertise that might be lost of the three laboratories were combined. Everyone with whom we spoke said there is good cooperation among the toxicology labs in HPB and in other federal Departments such as Agriculture Canada, Environment Canada and Transport Canada.

Program officials suggested there is room for more toxicity testing by industry. It is important that toxicity testing be replicated, and perhaps EHP toxicity testing could give this a priority. An assessment may stem from a single toxicity study done by a chemical firm, without replication by others; this is a concern.

There is much scope for identifying and using toxicity data from other countries. The EHP is active in the Intergovernmental Forum on Chemical Safety (IFCS). Rather than create a new international agency, heads of cooperating agencies in the International Program on Chemical Safety held a meeting in Sweden to establish this forum.

> There are 114 participating countries, which will meet next in 1997. IFCS also includes five UN agencies, intergovernmental agencies such as OECD, international science organizations, international industry and labour federations, and consumer and environmental NGOs. IFCS will meet every 3-5 years; between meetings, its activities are coordinated by an elected Intercessional Group and working groups. Canada is a member of the Intercessional Group and has lent Dr. E. Somers, former Director-General of EHD, to IPCS for two years to assist its Director with establishing a Secretariat.
>
> IFCS' program plans include:
>
> a. expanding and accelerating international assessments of chemical risks, by dividing assessments of chemicals among various countries, thereby allowing 200 additional assessments by 1997 and a further 300 by the year 2000;
>
> b. harmonization of classification and labelling of chemicals;
>
> c. information exchange on toxic chemicals and chemical risks;
>
> d. establishing a risk reduction program;
>
> e. strengthening national capabilities and capacities for the management of chemicals; and
>
> f. prohibition of illegal international traffic in toxic and dangerous products.

Participation in IFCS allows EHD access to much more information through international sources than Canada could ever hope to produce on its own, given current budgets. The program makes good use of opportunities to share information with counterparts in other countries. However, officials note that information sharing requires the Program maintain its own research projects in order to have something of unique value to exchange with international partners. To be a "player" in the international arena, one must have something to offer to the "game." Not only does this require the program to do independent research, it also requires international travel and conference attendance to develop and maintain contacts. But there are cuts and limits to international travel by federal officials. The time-consuming approval processes for international conference travel, while making sense government-wide, are creating problems for EHD.

> While travel to international conferences is often important for establishing contacts and exchange agreements, it should be increasingly possible in the near future to exchange toxicity data through electronic networks such as Internet. For example, the U.S. is currently posting scientific databases on Internet such as the U.S. Environmental Protection Agency Comprehensive Environmental Response, Compensation and Liability Information System and the ATSR's Hazardous Substance Release/Health Effects Database. Though North Americans are the leaders in the use of Internet for information and technology exchange, many countries have Internet connections and are expanding their use of them.

2.1.2 Exposure Information

According to Park *et. al.*, some of the CEPA assessments under PSL I did not contain sufficient information on human exposure levels and exposure routes to support the development of control options. It is important for CEPA assessments to focus on estimates of human exposure to environmental hazards and on the relationships between sources of these hazards and human exposure to them (exposure routes). Lack of analysis of how a substance enters the environment and how Canadians are exposed to it makes it difficult to decide on the most effective ways of controlling it.

- For example, the assessment documents for nickel indicated that food is by far the largest exposure source, and exposure from ambient air is some three to four orders of magnitude less. Nickel, however, was determined to be toxic on the grounds that it was an airborne carcinogen - the possibility of nickel in food was essentially not evaluated, because the data base was too limited. Also, there is no clear way to distinguish between anthropogenic sources of nickel and natural sources of nickel; such a distinction would bear on the control options one might adopt. (p 40)

- Consideration of exposure data and exposure routes might also affect regulatory priorities. Benzene is a carcinogen and therefore was declared CEPA-toxic. In reviewing exposure data, Park *et. al.* estimates that applying a hypothetical control option to the main source (the use of gasoline-powered vehicles) might result in saving one statistical death from leukaemia per year. It would be impossible to detect or convincingly demonstrate this small a health effect in mortality statistics; Park *et. al.* suggests this potential saving of one statistical death per year by applying their hypothetical control option could cost the industry and the consumer on the order of

$100 million a year.[30] There may be other CEPA-toxic substances for which control options might be less expensive and have a larger and perhaps more measurable public health benefit. Though the sort of analysis Park *et. al.* provides in their case report is approximate and may not be possible with other substances, it illustrates the potential utility of exposure information in setting priorities for developing control options. Exposure data and their analysis could also support the regulatory impact analyses now required of all Federal regulatory proposals.

- Identifying or collecting information on exposure levels and exposure routes for substances on the PSL II list may require more time and resources than were devoted to the PSL I assessments. Given the limited resources and severe pressures the PSL I workload placed on BCH staff, it would be important to set clear priorities among substances and to limit the number of PSL II substances to be subject to this more intensive analysis.

As noted elsewhere, information on exposure and on health impacts is generally more problematic than is toxicological information.

EHP officials told us the major exposure source for some of the PSL contaminants is the food supply; other sources are tobacco and indoor air. Tobacco products and by-products are thoroughly researched; indoor air is not well-researched or understood as a potential source of exposure to hazardous chemicals. Most of the discussion and disagreement on the adequacy of exposure information centred on the relationship between EHD and Food Directorate.

EHP interviewees expressed some dissatisfaction with information on PSL substances in the food supply. From their perspective, EHP officials believe the information is missing or out of date, due to delays in getting Food Directorate's market-basket survey finished and the data processed and reported. However, EHP officials recognize part of the problem is different organizational priorities in the two directorates. There have been formal discussions and letters of agreement to attempt a resolution of some of these difficulties.

Food Directorate officials say any information they have on a given contaminant is provided to EHD. If a substance is deemed toxic under CEPA, Food Directorate recognizes some continual monitoring of that compound is required to determine how levels and exposure in the food supply have changed. However, Food Directorate has other demands and priorities on its resources, which result in different perceptions on what is a manageable time frame for providing information on PSL contaminants in food.

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[30] A more detailed treatment of this topic may be found in the accompanying notes to M.G. Holliday, J.M. Park, P.W. Strahlendorf, and T.F. Schrecker, "The Canadian Environmental Protection Act: Science, policy, and public health," oral presentation at the World Environmental Congress, London, Ontario, 17-22 September 1995.

> When Food Directorate cannot comply in the time period EHD requires, it is usually due to a lack of resources. Many of the compounds on the PSL have not been found in food to date. Food Directorate is very reluctant to devote scarce resources to looking for substances in food that have not previously been found there.
>
> One possible irritant between the Directorates is the different approach taken by Food and EHD to hazard levels. Under CEPA, if exposure data suggest levels are more than 10% of the TDI (total daily intake) or other guideline, this has resulted in a ruling of CEPA-toxicity. This is more conservative than the approach Food Directorate takes; a finding of exposure more than 10% of the TDI guideline for a hazardous substance in food would not ordinarily result in any action by Food Directorate, unless it was accompanied with evidence this exposure level is part of a significantly increasing trend in the level. Substances that historically have shown such levels are not ordinarily given a high priority in Food Directorate's food analyses.
>
> Program officials are very satisfied with their access to epidemiological information from the Laboratory Centre for Disease Control (LCDC). BCH sometimes encounters problems in getting clear epidemiological information on carcinogenic effects, but this is a function of the long time it can take for such effects to show up in mortality and morbidity statistics and the difficulty in separating possible confounding variables in the analysis. These are scientific, not organizational, problems.
>
> Program officials say they are looking for new ways to further encourage research on exposure. They also indicated they would prefer CEPA to be amended to include a stop-the-clock provision for the time limits in assessing substances, for those cases where data crucial to the assessments are not available and need to be developed.

The scope for using international sources for exposure data is more limited than for toxicity data. Program officials told us toxicity data (how the human organism or animal analogues react to various toxic substances) are universal and can come from almost any country. However, exposure and exposure estimation is local or national, but not international, in nature, though research methods perhaps can be shared. Exposure data are generally not transferable, though toxicity data are.

> MMT (*methyl-cyclopentadienyl manganese tricarbonyl*) is an example of a substance for which exposure data are not necessarily transferable from other countries. A senior EHP official informs us this substance is considered hazardous by the US EPA partly on the basis of exposure hazards resulting from emissions building up near Los Angeles due

to temperature inversions. Comparable geographic and environmental conditions leading to hazardous exposure levels almost never occur in Canada in those areas where MMT is released into the environment. Hence, using common toxicity data but different exposure data and conditions, MMT was not placed on the PSL I list, though it is considered a toxic substance requiring regulation in the US.[31]

Exposure measurements and estimation procedures are not as standardized as are toxicological measurements and procedures. A senior program official expressed concern that if the current round of program reviews resulted in a devolution of environmental monitoring by Environment Canada to the Provinces, this would result in great difficulties for EHD to get exposure data. Instead of going to one source for information, EHD would have to go to twelve sources which would probably use different and perhaps non-comparable methods. This would greatly complicate health assessments under CEPA, which already suffer from a lack of good exposure information for some substances.

A proposed tissue bank as a source of exposure information.

Food Directorate conducts a breast milk survey, which is a source of exposure data from mothers. Medical Services Branch also has good data on mercury levels and organochlorines in adipose tissue and breast milk among people in the North and among Aboriginal people, but not as much use has been made of these data as could be. BCH is thinking of setting up a tissue bank to collect fatty tissues from cadavers to monitor levels of various hazardous substances. Some of these data are being collected through the Great Lakes Health Effects program.

Presently there is no comprehensive human tissue collection and monitoring in Canada. GLHEP spent nearly $200,000 planning such a bank, but the plans were cancelled. If one were to be developed, it could be housed in several other organizations, such as Food Directorate or LCDC. Program officials said the location of the bank does not matter, as long as it is established and EHD has access to the data. A tissue bank would be expensive to run and would require a long-term commitment by the Department for it to be of value.

2.1.3 Contracting out and cost recovery for CEPA assessments.

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[31] For more information, see "MMT-Gasoline Additive," Health Protection Branch *Issues*, November 27, 1992.

Environment Canada's recent program evaluation of CEPA suggests there are two alternatives to the current management of CEPA assessments: contracting out and reverse onus. [32] The report recommends these be studied, without stating a preference for either alternative.

Contracting out is opposed both by Environment Canada and Health Canada staff on the grounds of the use of confidential information, a shortage of expertise in Canada, loss of contractor learning to the government, and possible lack of consistency across the regulatory program. Commentators outside government who were consulted in the CEPA evaluation rejected all these arguments.

Some government interviewees in the CEPA evaluation wanted industry to be required to conduct or at least pay for risk assessments. Industry argues that, as US legislation places the burden of proof on the government, new substances regulations with reverse onus provisions would place Canadian manufacturers at a competitive disadvantage. There would be stiff industry opposition to such regulations, the CEPA evaluation concluded..

Program officials told us they are already contracting out as much risk assessment as possible. RPB has a very limited budget for contracts and can not do more than it is. There is little scope for further contracting out research work needed by BCH. Contracts already make up about 40% of BCH total budget and 60% of all BCH research. BCH contracts mainly the labour-intensive literature reviewing and other data sifting. BCH needs in-house expertise to evaluate the health implications of the toxicity and exposure data, as well as to monitor and assess contracted work when it comes in. BCH also needs to keep some research in-house to keep staff current and motivated.

BCH officials have not been satisfied with the contract work done in Canada. Most of their toxicology risk assessments are being done with a firm from the United Kingdom. On the first PSL, BCH needed a quick turnaround on the results. They found that the Canadian firms could not deliver on time and lacked the required scope and depth of experience. Canadian firms could not in their view produce work of the same quality as international firms, and the price was two or three times higher from Canadian firms. The Canadian firms' senior staff were so busy that BCH often found the firms' more junior staff actually were doing the work. This is not the case with the UK firms. The US firms do a good job, but they have difficulty doing the assessments to BCH specifications, typically following the different US EPA guidelines. A BCH official suggested the only satisfactory solution to getting Canadian contract work would be to bring Canadian contractors on staff through some kind of interchange assignment. BCH finds it takes about two years to train people in risk assessments. In the first year staff simply learn the techniques and complete no assessments.

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[32] Evaluation of the Canadian Environmental Protection Act (CEPA): Final Report, Evaluation Branch, Environment Canada, December 1993.

BCH is contemplating revenue generation for assessments of new chemicals. However, it may not make sense to charge for assessments of old chemicals. Unless only one firm uses a particular chemical, it is not clear who should pay for the assessment, nor how to apportion costs across several users. One might also note that charging the first firm to propose use of a new chemical the cost of the assessment, when other firms might also be interested in using it after approval, could inhibit firms from being the first to propose the chemical, thereby perhaps stifling innovation in the chemical industry.

2.1.4 Conclusions on Information Required for CEPA Assessments.

There is much scope for cost-effective sharing of information on toxicity through international programs such as IFCS. The Department should continue to support such efforts and the international travel which this sometimes entails.

It is important that future assessments under CEPA give priority to identifying or developing information on exposure levels and exposure routes for substances on the PSL II list. This may require more time and resources than were devoted to the PSL I assessments. Given the limited resources and severe pressures the PSL I workload placed on BCH staff, it will be important to set clear priorities among substances to be subject to this more intensive analysis.

Research on human exposure to toxic substances in the environment is especially a priority, not only because of the considerable information gaps and the central importance of exposure in establishing CEPA-toxicity, but also because exposure data often are not readily transportable or applicable from other countries. There is a strong rationale for a federal research effort in this area. There would be value in developing a national tissue bank to monitor exposure levels and establish trends for a wide range of toxic substances. *PED encourages EHD to explore with its sister Directorates in HPB the feasibility of establishing a tissue bank.*

2.2 COMPLETION OF CEPA ASSESSMENTS

Once completed, each CEPA assessment is published jointly by Environment Canada and Health Canada; copies are available from BCH and from Commercial Chemicals Branch of Environment Canada. Environment Canada and Health Canada completed the assessments of the 44 substances on PSL I within the deadline of February 1994.

Under Section 11(a): 15 substances were assessed as toxic; 17 were assessed as nontoxic; for 10 there were insufficient data for a conclusion; and for the remaining two, no assessment was conducted.

None of the substances were assessed as toxic under Section 11(b).

> Under Section 11(c): 18 substances were assessed as toxic; 13 were assessed as nontoxic; for 8 there were insufficient data for a conclusion; and for the remaining 5, no assessment was conducted.

Health Canada was the "lead department" for 19 of the substances, with Environment Canada being the lead on the other 25. The complete list of PSL I substances, the lead department, and the final assessments under Sections 11(a) and 11(c) appear in Table 2-1 of the case study report by Park, Holliday and Vardy (p. 12).

The feedback PED has received on the quality of the published PSL I assessments has been uniformly, and strongly, positive. Park et al. concluded that "in general, the assessments are scientifically defensible; the major hazards have been identified, and estimates of their degree have been made using informed scientific judgments."[33]

> "The effort needed to carry out the toxicity assessment of 44 priority substances within a nominal period of five years -- and in practice probably not much more than half that time -- with the resources available to Health Canada is extreme. ... By any standards we -- and our respondents -- feel that the quality of the assessments is high. Given the intense time pressure under which they were produced, their quality is outstanding, and we believe the individuals responsible for producing them deserve the strongest commendation for their efforts."[34]

> RFI support this assessment through the results of their interviews: "Consultations aside, a number of individuals commended EHD for its science-based approach and for 'sticking to their mandate.' Adjectives such as 'precise,' 'exact' and 'credible' were used. Other (interviewees) were however critical of what they perceive as an unwillingness to enter into discussion and debate on issues regarding the assessments. ... Some suggested (this resulted from) EHD's role to provide scientific advice and not to act as an advocate or to enter into political debate. Others suggested that constrained resources inhibit EHD officials from doing more ... they cannot afford, it is felt, to become embroiled in time-consuming debate over scientific advice and risk assessments."[35]

As Park et al. note in their report, and as PED was told forcefully in several interviews with program officials, Health Canada met its deadlines and responsibilities in preparing the CEPA assessments at considerable human cost, in terms of stress and workload on staff, as well as general frustration with some aspects of the process. The costs and frustrations may be summarized as follows.

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[33] Park, Holliday, and Vardy, 1995, p. 25.

[34] Ibid., p. 49.

[35] RFI, 1995, p. 9.

> There has been general agreement among government personnel that management underestimated the time and effort that would be required to do the assessments; this point was made both in the Environment Canada evaluation and in interviews and conversations during PED's evaluation of EHP.
>
> As the Environment Canada evaluation notes, both departments experienced considerable start-up problems, though Health Canada did not have to develop new skills, since health risk assessment was relatively well-established in EHP already. Environment Canada had to development new analytical skills, hire new staff, and implement new systems. This created considerable friction between the two departments at the early stages, though the problems seem to have been ironed out by now.

Park et al. note the initial plan was for PSL assessments to be produced using task groups formed with staff from both departments. Few assessments were actually produced in this way, however. Reasons given for abandoning this approach included:

> group leaders had little direct control over group members, notably (according to PED interviews with EHD staff) those from the other department or from outside their own chain of command within their department;
>
> inconsistencies in the reports produced by different task groups;
>
> lack of quality control by management, notably (according to PED interviews with EHD staff) from Environment Canada;
>
> in the minds of some individuals, the assessments were being produced too slowly this way.

Eventually, most assessments were in fact produced by the indicated lead department, with input and comment from the other department. The resulting workloads and stresses within the BCH Divisions involved were heavy and, PED has been told, produced substantial resentments among staff arising from perceived inequalities of workload across the Bureau and management's inability under present resource and staffing constraints to reward some of the exceptional efforts that were made.

There are grave concerns, both in Environment Canada and especially in Health Canada, concerning the program's ability to continue to meet CEPA assessment workloads and deadlines with current resources, especially in light of sunsetting Green Plan funding for CEPA. This concern is most cogently summarized in Environment Canada's CEPA evaluation (p. 126):

> "It was evident early on that the resources available for the PSL assessments were inadequate. The shortfall was corrected with Green Plan funds, which are estimated to provide in the order of 55% of total annual funding for PSL assessments in both Health Canada and Environment Canada. Assuming that PSL2 imposes approximately the same demands as PSL1 did, unless the Green Plan money is renewed or added to the A-base at the termination of Green Plan funding, neither Health Canada nor Environment Canada will be able to meet its obligations under PSL2."

2.3 SUGGESTIONS FOR IMPROVEMENT OF THE CEPA ASSESSMENT PROCESS

RFI reported mixed feelings among interviewees about the PSL I consultation process. Some interviewees were satisfied with it, others ("perhaps the majority") were not. Dissatisfaction applied equally to governmental and external stakeholders, generally focusing on the limited extent of the consultation and the lateness in the process. Interviewees admitted, however, that lessons have been learned from PSL I, which it is hoped will be applied in the PSL II processes.

Park et al. noted, "some of our respondents were highly critical of the process by which the first set of Priority Substances was chosen. Indeed, we can sympathize with those who, working under the pressure of the five-year deadline, found themselves having to spend time conducting assessments on substances that, for example, were not present in the Canadian environment." [36] The consultants endorse the new criteria the two departments have proposed for PSL II, which appear to PED satisfactorily to accommodate this concern.

PED interviews uncovered various concerns and possible areas for improvement.

> BCH staff are concerned about how they are to address (and find resources for addressing) PSL I substances if and when new toxicity or exposure information comes available; examples cited were lead, dioxins, and furans. There is also a concern about whether and how to proceed with those substances for which there was 'insufficient information to assess' under either Section 11(a) or 11(c).
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> PED was told LCDC was involved in only one or two meetings on the PSL I assessments and that Cancer Division staff were not involved in the reviews of carcinogenic substances. Though LCDC staff are not familiar with the CEPA

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[36] Op. cit., p. 53.

> assessment process, some feel it might be beneficial for them to be involved in future assessments.
>
> Air, food, water and consumer products are the main exposure routes for PSL substances. Program staff expressed a need to improve coordination and priorities within HPB among Directorates in getting exposure data. A start has been made informally through a CEPA toxic work team.
>
> BCH staff also feel there is not sufficient coordination and integration between their Bureau and Health Promotion Division for public risk and risk management communication; PED found some sympathy and interest at the working level in Health Promotion Division for a better and closer working relationship with BCH. This desire for closer working relationships was not specific to CEPA, but extended to all BCH's responsibilities.

The House of Commons Standing Committee on Environment and Sustainable Development released its June 1995 report on CEPA as PED was writing its program evaluation report. PED reviewed the Committee's report and found it contained a number of conclusions and recommendations which bear on the pace at which CEPA assessments have been completed.

> "The overall concern (with the PSL process) was that it will take much too long, and perhaps prove impossible, to deal with the larger number of potentially toxic substances in our environment, if it continues to require five years to complete a risk assessment of fewer than 50 substances."[37] The committee accepts an argument by a witness (p 65) that the current definition of toxicity is so strict as to reduce the effectiveness of CEPA by making it too hard to declare a substance toxic under the Act.
>
> The report comments on "the unacceptably slow assessment and control of toxic substances ...".[38] On page 278, the Committee report states, "the current risk assessment standard in CEPA imposes too stringent a precondition to the development of measures to prevent or control the generation, use or release of toxic substances. In some cases, the inherent hazard characteristics of a substance should be sufficient to justify regulatory intervention to prevent or strictly control its generation and use."

2.4 HEALTH HAZARDS IDENTIFIED IN THE CEPA ASSESSMENTS

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[37] Op. cit., p. 64.

[38] Op. cit., p. 275.

It would be difficult and probably futile to attempt to summarize in a few paragraphs all the health hazards identified and addressed in the CEPA assessments, as the substances and the specific hazards are wide-ranging and very different one from the other. Instead, PED has prepared a detailed chart summarizing the major health risks identified in the CEPA assessments (see PED's "Priority Substances List Reports Summary" in Appendix E to this report). Readers are invited to consult the chart and, if interested in further information, to consult the relevant published assessment reports.

Generally, the health risks identified under CEPA fall into two types: threshold toxicants and non-threshold toxicants. For the former, it is believed there is a level of exposure (threshold) below which there is no significant risk to human health. For the latter (most carcinogens) there is believed to be some risk at any level of exposure. Park et al. reported to us that, although many assessments address significant health hazards, this approach has produced a few anomalies among the CEPA assessments:

> "The EHD has decided that for the purposes of CEPA toxicity assessments there is no *de minimis* risk for carcinogens, and accordingly any human carcinogen is deemed CEPA toxic, whatever its levels in the environment. . . . One consequence of using this approach is that once a substance is identified as a human carcinogen, for the purposes of assessing its CEPA-toxicity, a thoroughgoing exposure assessment is unnecessary. This may result in a major saving of effort (for the assessment phase), but puts an increased burden on the control options phase: until it is understood how a substance enters the environment and how Canadians are exposed to it, it is difficult, if not impossible, to decide on the most effective ways of controlling it."[39] The report discusses the example of the chloromethyl ethers (section 3.1.1, pp. 17-18) which as carcinogens have been declared CEPA-toxic but which, because of current exposure levels and their short persistence properties, "cannot realistically be said to present any public health risk."

The House of Commons Standing Committee on Environment and Sustainable Development, in its June 1995 report on CEPA, proposed changing the rules of evidence for declaring a substance CEPA-toxic.

> "The Committee recognizes that the current provisions in CEPA regarding existing substances reinforce the view that all chemicals are innocent until proven otherwise. In the interim, Canadians and the environment are at risk. Chemicals may be used for long periods before their dangerous effects are known. We believe that another approach is required when dealing with potentially toxic substances. ... Although CEPA currently contains some provisions authorizing the government to require information from

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[39] Op. cit., p. 17.

> importers and users of substances, the burden of proof is still on the government to establish that a specific substance is toxic. Providing such proof is especially difficult when there is little or no toxicological data or other information. In such cases, the government must then incur significant expense to obtain the required evidence. The Committee recognizes that to prohibit all substances until they are deemed to be safe would, in effect, stop all industrial activity in Canada. Equally important, it would be just as unreasonable to demand that polluters demonstrate that a substance is absolutely harmless, as it would be to require governments to show absolute proof of toxicity." [40] The Committee argues however that "all provisions in CEPA should be based on the principle that users/producers must ensure that the substances they produce, use or sell do not pose an unacceptable risk to the environment or to human health."[41]

Recommendation 9 of the Committee report proposes amending Section 11 of CEPA to allow for the use of an "inherent toxicity approach (as well as a risk-assessment approach) in determining whether a substance should be designated as toxic under the Act." The Committee proposes the Governor in Council promulgate regulations prescribing the standards of assessment to be followed in doing this. One of the principles the Committee proposes be used in assessing toxicity is the "weight of evidence" principle; the Committee accepts for this purpose the International Joint Commission's definition of the term, which "means taking into account a variety of studies across a range of circumstances and then, if there is a strong tendency or probability of linkages between the substance(s) and injury, taking action to stop the input of those substances to the environment without waiting for absolute proof that a specific chemical has caused injury to humans."[42]

The Committee also recommends the adoption of "user/producer responsibility," which it defines as follows: "for all substances suspected of posing a serious threat to the environment or health on the basis of weight of evidence, the onus shall be on the proponent or producer to demonstrate that the substance is safe, rather than on government or concerned citizens to prove that it is harmful."[43]

The Committee proposes the practice of sunsetting of substances. It defines sunsetting as "an emerging concept which allows a substance or process to be characterized as harmful to human or ecosystem health and scheduled for virtual elimination from the environment over a sufficiently long period of time for substitute substances or processes to be put in place, with minimal disadvantage to society."[44] The Committee proposes the substances be proposed for sunsetting if they are environmentally persistent, bioaccumulative, inherently toxic and predominantly anthropogenic. A full risk assessment would not be required to justify sunsetting of such substances; instead, stakeholders, producers and users of such substances would be consulted on a schedule for elimination and "should have an opportunity to appeal such a decision and demonstrate extraordinary reasons why the substance in question should not be sunsetted." [45]

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[40] Op. cit., pp. 57-8.

[41] Ibid.

[42] Op. cit., pp. 317-8.

[43] Op. cit., p. 317.

Effectively, the Committee's proposals would shift the burden of proof concerning regulatory impacts from government to industry. Presently it is incumbent upon the government to demonstrate that the probable health benefits of a regulatory proposal justify the probable costs of implementing that proposal. The Committee's proposal would, for substances deemed for sunsetting, shift the burden to industry to prove the costs of the regulatory proposal are extraordinary and outweigh the probable health benefits.

The Committee's Recommendation 20 proposes a stop-clock provision where there is insufficient information to complete a PSL assessment; the recommendation says Industry should have one year after the clock is stopped to provide the needed information to Government. If after one year that information is not forthcoming, the Ministers could declare the substance toxic and control it. Again, the onus of proof is shifted to the industry.

For at least some of the PSL substances, the proposed shifting of burden of proof to the industry would seem to change BCH's role from producing scientifically defensible assessments to reviewing and verifying or critiquing assessments done by industry. The result could well be a lowering of the BCH workloads for completing individual assessments and a greater ability for BCH to assess more substances with the same resources.

2.5 CONTROL IMPLEMENTATION STRATEGIES

Control implementation strategies for PSL I substances are under development at the time of this writing. There is nothing to report at this time about the consultations, regulations, guidelines or standards mentioned in the evaluation question wording.

As Park et al. note in their report, it was decided early in the PSL I assessment process to focus on risk analysis and to defer the development of control strategies until after completion of the assessments. The reasons for this were the insufficiency of resources to permit working both on toxicity assessments and on control strategies at the same time, as well the desire to avoid unnecessary work on control options for substances that eventually were decided not to be CEPA-toxic. However, Park et al. suggest that a lack of analysis in the assessment reports of how a substance enters the environment and how Canadians are exposed to it makes it difficult to decide on most effective ways of controlling the substance (a similar observation appears in the Environment Canada CEPA evaluation report, page 42). Park et al. Once control implementation strategies are developed, there will be an expectation among industry, Treasury Board, and parliamentary circles that these strategies be cost-justified. This would not be easy under the present "rules of evidence" governing CEPA risk assessments and regulatory impact analyses of control options.

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[44] Ibid.

[45] Ibid., pp. 73-74 *passim.*

The Environment Canada evaluation of CEPA notes that federal regulatory policy requires regulatory proposals to demonstrate, among other things, that total benefits of the proposed measure exceed all associate costs.[46] The report concludes that most of the assessment of the benefits in CEPA RIAS (regulatory impact assessment statements) statements "are inadequate. With the exception of the ODS (ozone-depleting substance) regulations, little effort is made to quantify benefits."[47] The report acknowledges there are difficulties in valuing environmental benefits, but appears to agree with the House of Commons Finance Committee in its criticism of Environment Canada's failure to provide quantitative estimates of the benefits of regulations. "A number of basic issues concerning the evaluation of regulations have not yet been resolved, including how the value of a life is to be quantified and how much the government is willing to spend on a good cost-benefit analysis."[48]

Park et al. share the concern of EHP program staff "over Environment Canada's insistence on quantitative risk assessment in the development of control options. This disquiet stems from the view that the order-of-magnitude uncertainties associated with such (health risk) assessments make quantitative estimation of the benefits associated with a particular control option impossible."[49] The report gives three examples of the difficulties in applying quantitative health-risk assessment to an analysis of control options (p. 43-45).

PED appreciates the complexities and concerns Park et al. cite. However, we believe it is all the more important that EHP have on staff health economists able to provide cogent benefit analyses where this is possible and to provide to external stakeholders credible arguments on the limitations of doing so where it is not.

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[46] Op. cit., p. 47.

[47] Ibid., p. 49.

[48] Ibid., p. 50.

[49] Op. cit., p. 36.

The House of Commons Standing Committee on Environment and Sustainable Development recommended that CEPA incorporate the principles of "sustainable development" and the "precautionary principle." PED believes this recommendation has implications not only for toxicity assessments but also for the development of control options.

> The definition of sustainable development adopted by the Committee is "development that meets the needs of the present without compromising the ability of the 'next seven generations' to meet their own needs." [50] Depending on how one calculates the length of a human generation, this implies that both risk assessments and control-option analyses adopt a time horizon of at least 200 years in estimating health, environmental, and economic impacts. One can argue that economic and opportunity costs from regulatory controls are relatively short-term; perhaps within five or ten years of the adoption of a regulatory control, either an industry adapts efficiently to the control or it declines and (one hopes) the employees and financial resources dedicated to that industry are adapted to other productive efforts. Health and environmental impacts from the failure to control a serious environmental contamination problem continue to multiply for the full 200 years of the time frame. If one incorporates a seven-generation time horizon for the regulatory impact analysis, the balance of the importance will likely shift from economic and opportunity costs to health and environmental benefits.
>
> The adoption of the Precautionary Principle within CEPA will reinforce this change in emphasis from economic costs to health and environmental benefits of regulation. The Committee defines the Precautionary Principle as follows: "in respect of all substances suspected of posing serious threats to the environment or to human health, on the basis of weight of evidence, lack of full scientific certainty shall not be sufficient reason for postponing preventive or remedial measures." [51] . . . "The precautionary principle favours erring on the side of human health and environmental protection rather than on the side of short-term economic growth."[52]

2.6 INDICATORS OF THE HEALTH CONTRIBUTION OF CEPA ASSESSMENTS.

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[50] Op. *cit*., p. 317.

[51] Ibid., p. 316.

[52] Ibid., p. 54.

"Obviously, CEPA assessments by themselves can have no measurable effect on human health. Only when control options are developed and implemented can one hope that CEPA-related activities will begin to bring about improvements in human health."[53]

CEPA assessments, and EHP's contributions to those assessments, contribute to the health of Canadians very indirectly. The health-risk assessment information in the CEPA documents will inform and guide the development of control strategies. The administration of these strategies will, one hopes, reduce human exposure to toxic substances, which over time will presumably improve the health of Canadians, or at least prevent adverse health affects that might otherwise have been developed. The measurement and demonstration of these health effects through changes in morbidity and mortality statistics would at best take decades to accomplish and would be problematic to prove or link back to the Program's efforts under CEPA.

The problems in drawing these links are summarized earlier in this chapter (see pages 67 - 74). The Environment Canada evaluation of CEPA also recognized these problems, though it expressed optimism some limited indicators of beneficial health effects can be found:

> "It is difficult to determine the direct environmental and health impacts of CEPA for three reasons. First, it is too early to tell what impact CEPA is having on environmental quality and human health; relatively few regulations have been developed and only a relatively short time has passed during which these regulations could be expected to produce tangible effects. Second, it is difficult to separate the effects of actions taken under CEPA from other factors, such as provincial actions, green consumerism, industrial changes due to the recession, free trade and technical advances. Third, data and knowledge related to health and environmental conditions, toxic levels, and cause and effect relationships are limited. There are many data gaps, and the understanding of impacts is particularly weak at the ecosystem level."[54]
>
> "... Indirect effects may be more important than any direct effects. It is virtually impossible to attribute these indirect health and environmental impacts exclusively to CEPA as many other factors are involved. All that can reasonably be asked is whether CEPA's indirect effects are moving action in the right direction - are they supporting or undermining overall efforts to improve health and environmental conditions?"[55]

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[53] Park et. al., p. 46.

[54] Op. cit., p. 128.

[55] Ibid., p. 131.

> "Scientists at Health Canada believe it is impossible, in most cases, to link environmental effects directly to health effects. Health Canada therefore intends to rely on Environment Canada information concerning environmental impacts to help judge the efficacy of CEPA control measures. We note, however, that Health Canada is doing research on health and environmental linkages (e.g., its Health and Environmental Action Plan). Moreover, a considerable amount of monitoring information is collected by other jurisdictions and universities on health and environmental linkages. The possibility of integrating this research with the specific information required to evaluate CEPA's health impacts should be investigated."[56]

> "The evaluation of CEPA's results is complicated by the fact that some of the information needed to assess the impact of CEPA is either not being collected or is not being reported in a way to allow cause and effect relationships to be established. Nevertheless, some evidence of direct health and environmental impacts can be discerned, including reductions in emissions of ozone depleting substances, lead in gasoline, phosphates in detergents, and in dioxin and furan levels in fish downstream of pulp mills in British Columbia."[57]

Park et al. expressed the following reservations about developing indicators of the contributions of CEPA to the health of Canadians:

> "The middle range of levels in exposure media seems to be the most useful (of indicators). But levels of environmental contaminants in Canada are low, with the result that the associated incidences of environmental illness are also low, and it would therefore be very difficult to obtain enough reliable data from which to draw conclusions about the effects of individual contaminant levels on human health."[58]

3. EFFECTIVENESS OF PROGRAM ACTIVITIES UNDER THE RED ACT

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[56] Ibid., pp. 135-6.

[57] Ibid., p. 141. Holliday and Associates have pointed out to PED that only one of the examples cited was the subject of a CEPA assessment, namely dioxans and furans. Ozone depleting substances were not assessed, since they were already dealt with under the Montreal protocol; lead in gasoline and phosphates in detergents were regulated before CEPA came into operation.

[58] Park et. al., p. 47.

EHD's administration of the Radiation Emitting Devices Act and Regulations is the responsibility of the Radiation Protection Bureau. Activities under this Act include: the drafting of regulations; testing and inspecting devices; providing advice to manufacturers, provinces and users; carrying out or participating in compliance and follow up actions. During the course of this evaluation, a reorganization of the Health Protection Branch resulted in the Radiation Protection Bureau taking over responsibility for inspection and compliance actions of the former Field Operations Directorate.

Activities under the RED Act are also related to the activities of other legislation such as the Canada Labour Code (CLC), Food and Drugs Act (FDA), Treasury Board Standards (TBS), Atomic Energy Control Act (AECA), and the Department of National Health and Welfare Act (DNHWA).

In Fiscal Year 1994-95, RPB had 75.4 Full Time Equivalents (FTEs) and a total budget of $5.8 million. RPB consists of three Divisions: Environmental Radiation Hazards, Occupational Radiation Hazards and Consumer and Clinical Radiation Division. This program evaluation focuses mainly on the activities of the X-Ray Section and the Non-Ionizing Radiation Section of the Consumer and Clinical Radiation Hazards Division; in FY 1993-94 these sections consumed respectively 11 and 10 FTEs.

The X-Ray Section conducted 339 inspections of equipment or facilities in 1993/94; in 62% of these, the equipment or facilities were found fully compliant. In the remaining 38%, problems were identified requiring corrective action and follow-up. This was a fairly representative year; in the three years preceding, compliance rates varied between 55% and 68%.

The Non-Ionizing Radiation Section's activities are reported differently from those of the X-Ray Section. During the four years ending with FY 1993-94, the Section devoted between 4 and 10 person-months per year to the drafting and maintenance of regulations. Annual fluctuations are not meaningful, as the preparation of a particular regulation may extend over more than one year, and the intensity of involvement varies with the stage of preparation. Evaluation of devices by the Section varies substantially from one year to the next, depending on the characteristics of the particular devices and regulations involved. In the four years examined, the Section conducted between 67 and 169 device-compliance evaluations of routine submissions per year and several detailed evaluations, using between 7 and 16 person-months.

In 1993/94 the NIR Section devoted nearly 70 person-months to inspections and related radiation-safety activities in Federal Departments, completing 18 routine submissions and assessment 127 devices.

The NIR Section devotes substantial resources to addressing public concerns about non-ionizing radiation; in 1993/94 the Section devoted 24 person-months to addressing 900 public enquiries and another 14 person-months to related literature reviews and hearings.

3.1 EFFECTIVENESS OF EHD'S ADMINISTRATION OF THE RED ACT

The effectiveness of EHD's administration of the RED Act and Regulations is indicated by the planning and resourcing of its activities under the Departmental's risk management framework and by industrial and institutional compliance with the Act.

3.1.1 Planning and resourcing.

The Bureau's planning and resourcing activities are reflected in the Bureau's PARs and other documents described below. For most of these activities RPB uses the risk assessment and management framework. The Bureau's planning activities are also affected by public and media perception of health risks.

The evaluation team found from its interviews with program officials that RPB makes use of the risk-management framework on a regular basis. One of the problems in applying that framework to the Bureau's planning and priorities is the political pressure arising from public perception (and sometimes misperception) of risk. If a vocal portion of the public perceives a risk, then RPB has to assess that risk whether or not there are *a priori* scientific grounds for assuming there is a probable and important health risk. For example, RPB extensively tested cellular phones and has not found any health risks from them.

Planning documents from the Radiation Protection Bureau show that planning of priorities is based in the risk assessment and risk management concepts of the framework. The Bureau's annual Project Area Reviews, the core planning documents of the Bureau, are based in the risk management framework. As part of the preparation of Project Area Reviews, "A Proposed Activity Evaluation and Priorization Framework" document was prepared by RPB [Health and Welfare Canada (November 5, 1991)]. This document shows a two-phase evaluation procedure for the priorization of non-ionizing radiation emitting devices; the same two-phase evaluation procedure is also used for radiation emitting devices.

Ionizing and non-ionizing radiation health issues were identified as two of the 49 major health priority issues faced by the Health Protection Branch [Health Canada (October 1, 1993)]. These health issues were identified using risk assessment and risk management concepts [Health Canada, Radiation Protection Bureau (undated-b), Health Canada, Radiation Protection Bureau (undated-c)].

Most recently, in the HPB's Health Risk Communication Handbook [Health Canada (March 1994)], RPB's radon study was used as an illustration of the risk communication practices of not only RPB but the Directorate. Again, this report was based in the risk management framework.

The Bureau has used the risk management framework to influence international standardization. The International Electrotechnical Commission has adopted the risk management framework through the effort of its working group member from the X-Ray Section.

The Theratronics case study [Gunter et al. (March 22, 1995)], which was conducted under contract for PED, recommended that EHD make full use of the HPB risk management model in the management of risks associated with cobalt 60 teletherapy and treatment planning systems. The study found that EHD did not make full use of the risk management model in all the areas where the principles of the model might have been applicable. The report makes some suggestions as to how this might have been done and might be done in the future were required. The case study did find that RPB responded promptly to an emergency situation where its advice and expertise were required, supplying technical reports of high quality, demonstrating in-depth knowledge of the equipment and the requirements of the treatment centres.

> **In conclusion, the planning and resourcing of EHD's administration of the RED Act and Regulations are done in accordance with Departmental's risk assessment and risk management framework.**

3.1.2 Administration of the Act

As part of its activities for identifying and assessing high-risk devices, RPB maintains a list of radiation-emitting devices. RPB prepares draft regulations, guidelines and safety codes, and it conducts regular X-Ray inspections of federal facilities and other evaluations and surveys on request. RPB also monitors publications for evidence of hazards in devices, and investigates concerns brought to its attention. The Bureau also has introduced a Quality Assurance Program, which it disseminates through workshops and lectures to its clients and stakeholders.

Program officials commented that RPB activities for identifying and assessing high-risk devices do not include any additional pre-market or post market surveillance of devices. The RED Act and Regulations do not require any pre-market review of radiation emitting devices, and RPB does not have the resources to conduct such surveillance. As far as PED can determine with the evidence available, RPB clients seem to be satisfied with the present system. PED found no evidence to suggest there are major radiation-emitting devices that pose health risks that EHD has not been able to manage adequately. Program officials indicated, however, that private importation of devices (e.g. toys with laser beams) could represent risks to the Canadian consumer. In these cases the Bureau has no regulatory control.

The documents that PED examined reinforce the findings of the RFI study [Resource Futures International and the ARA Consulting Group Incorporated (May 24, 1995)] and echo the opinions expressed by Health Canada officials in PED interviews. Industrial and institutional compliance is not a concern.

Most RPB compliance and enforcement activities under the RED Act are carried out by the X-Ray and Non-Ionizing sections of the Bureau. These sections conduct inspections as part of these activities. These activities are described below, Appendix B gives a detailed description of RPB inspections.

X-Ray Inspections. RPB documents show that there is no formal inspection plan for x-ray emitting devices. The RED Act does not provide for any routine testing of devices. The checking of equipment against the requirements of the RED Act is part of RPB's survey procedure. RPB inspects X-Ray equipment operated in federal facilities and in jurisdictions having an agreement with the Health Protection Branch (Prince Edward Island, Northwest Territories and Yukon). Safety Codes and guidelines are developed to conduct these inspections and to help RPB clients. Requirements on equipment and facilities specified in safety codes have the force of legal x-ray safety standards within federal departments, and where referenced in Canada Hazardous Substances Regulations, in all workplaces covered by the Canada Labour Code. These are advisory documents outside the federal jurisdiction, but they serve as a reference for provincial radiation safety legislation.

The usual survey cycle for x-ray inspections is from two to five years. In addition to inspections, the X-Ray Section processes voluntary submissions and tests in its laboratories equipment it requests from manufacturers for regulatory evaluation.

The focus of the X-Ray Section is to persuade user groups to operate their own quality assurance programmes. Thus the work becomes auditing with spot checks and the inspection of new or modified equipment. It should be noted that this project consists of ad-hoc spot checks, and it is not part of any formal pre-market review of radiation emitting devices. Such a quality assurance program has been successfully introduced in PEI and the Yukon.

X-Ray inspections are a cost-recovery operation; federal facilities cover the cost of inspection travel. The estimated cost for Inspections of federal facilities is $30K for fiscal year 1993-94.

Table 6 in Appendix B shows that most industries and institutions inspected by the X-Ray Section are compliant. In 1993/94, the section conducted 339 inspections of which 210 (62%) were compliant and 129 (38%) had problems with the equipment. Normally, all of the institutions with problems in their equipment correct them during or after the inspection.

Non-Ionizing Radiation Inspections (NIR). NIR inspections differ from X-Ray inspections. NIR inspections are typically carried out in response to a specific request, in most instances triggered by workers' apprehension about possible risk of using a device or working in a facility.

The NIR Section also finds that industry/institutional compliance is very high for NIR devices. As with X-Ray inspections, there is always a follow-up in the case of a non-compliance found in an NIR inspection. When the problem is not corrected during the inspection visit, the owner must submit information that it was corrected subsequently. This is verified during a subsequent visit.

The Bureau conducts information sessions as part of the inspection program; it also conducts workshops [Dvorak, Pavel and Paul Chaloner (1989)] and seminars (Quality Control Monitoring, September 1993).

Program officials stated that RPB deals with a mature, large industry that is eager to comply. The industry uses its compliance with the RED Act and Regulations as a marketing tool; customers are willing to purchase products they know to be in compliance with the Act and Regulations. Officials told PED that RPB has had a few cases where companies did not comply with the RED Act and Regulations. These companies are now in compliance or are no longer in business.

A problem with compliance, over which RPB does not have any regulatory control, could arise on occasions with private importation into Canada of consumer products that have radiation hazards that producers or consumers may not be aware of.

Regional involvement under the RED Act is reactive, not proactive. The Regions only respond to enquiries on power lines, UV, radon, electrical blankets, etc. There is no regional involvement in the X-Ray inspection program, which is carried out through federal/provincial agreements that do not typically involve the regions. Regions do get involved in medical device inspections and recalls, doing follow-up. Regions are much more involved with Food and Drugs Act inspections than with RED Act inspections.

There may be opportunities for more linkages between the Regions and RPB, because medical devices are being inspected by regional office staff. Inspections of other radiation emitting devices could in theory be included at the same time. There has been little regional involvement in RED compliance inspections by Ottawa-based RPB personnel, as presently Regional staff do not have the training and experience necessary to inspect radiation-emitting devices. Many REDs are co-located with medical devices; as Regional staff get integrated with the other Directorates in HPB, presumably joint inspections will become more common. When Ottawa experts were testifying in Atlantic Region regarding aircraft noise in Labrador, the Region was not involved. However, visiting experts from Ottawa are getting better at informing and briefing regional staff.

The RFI interviews found that compliance with the RED Act and Regulations is not an issue, as more than one individual pointed out. Quite simply, it is in the interests of industry and institutions to comply with regulations because of worker concern for radiation hazards, real or perceived, and because of "the intelligent understanding that we cannot have unregulated radioactive sources".

Enforcement of the RED Act also appears not to be an issue. The Radiation Protection Bureau (RPB), which has jurisdiction over the sale and importation of radiation emitting devices and over federal and territorial facilities and operations, does not have a large monitoring program. Monitoring of operating equipment in all other instances is handled by provincial inspectors. RPB may become involved in some situations which are overlooked by other jurisdictions, or in which RPB has been asked to consult.

3.2 ARE CHANGES NEEDED TO THE RED ACT?

Opinions on whether changes were needed to the RED Act and Regulations were diverse among program officials. Program officials that favour changes to the RED Act commented as follows.

- Changes to the Act in 1984 allowing general application rather than specific regulations have made RPB's work much easier.

- Some RPB officials would like to be able to reference ISO standards or other international standards, rather than having to write new regulations or standards. Harmonization under NAFTA may actually help RPB to do this. It is important that RPB keep its connections and memberships on international standards committees.

- Presently RPB is investigating the possibility of using national or international standards in lieu of regulations. Program officials find standards and guidelines preferable to regulations, as the technology in the field of REDs changes so fast that any regulation is likely to become outdated quickly. It takes a very long time to get new regulations through the formal regulatory approval processes.

- Some Program officials observed that the Act is very prescriptive on standards; this is out of line with other parts of HPB's regulatory and legislative framework. Unlike other legislation enforced by HPB, such as the Food and Drugs Act, the RED Act and regulations have not been reviewed in the same manner as the Food and Drugs Act.

Some officials stated that there is no provision in the act for Good Manufacturing Practices; and that these might work in this industry. Officials asked, instead of legislating standards, why not have more general regulations? With the exception of laser rays in toys (see above), no other specific devices were mentioned as problems requiring new regulations.

- Some officials said that a complete revision of the RED Act may be necessary. Presently, the Act provides only for writing of standards for specific devices. There is no systematic inspection of devices, with some exceptions, e.g., television receivers. RPB's management of radiation hazards is often reactive rather than proactive.

RPB's clients within the Department had no suggestions for changes to the Act or regulations.

RFI interviewees commented that the provinces rely on federal legislation, safety standards and codes as benchmarks for the design and functioning criteria for radiation emitting equipment. Provincial respondents reported that, in their experience, the RPB is "readily available to respond to queries pertaining to radiation. Their expertise is frequently used."

The RFI interviews provided no indication of a need for changes to the Act or Regulations. RFI suggests in their report that this may be a function of the limited number of individuals interviewed on this topic, or simply that there is nothing, as far as they are concerned, that needs to be fixed. Mention was made, however, of the need for ongoing attention to updates, and the provision of these updates to the right people.

The Theratronics Case study [Gunter et al. (March 22, 1995)] suggested there may be a need for changes in regulations governing radiation-therapy devices. The case study recommended that EHD explore, in concert with other regulatory entities (both within Health Canada and outside), the possibilities of providing more regulatory attention to the safety of the patient undergoing radiation therapy treatment.

It should be noted that the study restricted itself to the federal level to arrive to this conclusion; the contractors had neither the mandate nor the budget to interview provincial officials regarding the provincial role in the safety of patients.

In examining the statutory considerations of AECB, Holliday and Associates noted that AECB has no jurisdiction regarding the safety of patients. The study noted that the prime responsibility for the patient safety lies with the treating physician; physicians are licensed to practice by the province in which they work. Physicians, in turn, rely on the services of medical physicists and medical radiation technologists (individuals that are also licensed by the provinces) to develop the appropriate radiation treatment regimes.

By this reasoning, the prime responsibility for patient safety lies within provincial jurisdiction.

The consultants' report also raises some concerns about the appropriateness of the actions of the former Field Operations Directorate regarding certain Theratronics products. PED does not consider there is any continuing cause for concern on this matter. Even without hearing the former FOD officials' side of the case, it can be argued that under the circumstances of the day, the stop-shipment actions were prudent; inaction arguably would have been less defensible. The consulting report is not critical of any of the advice given by RPB and in fact is complimentary in that regard. The former Field Operations Directorate no longer exists, and its responsibilities and resources are being integrated with those of the various "line" directorates in HPB, including EHD, so the prospect of future lack of consultation or coordination in this area seems highly unlikely.

The scope of this Environmental Hazards program evaluation did not include the Department's capability to respond to environmental emergencies. However, senior program officials whom we interviewed expressed grave concern about the impact of limited resources and further resource cuts on RPB's ability to meet its responsibilities under FNERP (the Federal Nuclear Emergency Response Plan). There remain worldwide concerns about the possibilities of future nuclear reactor accidents, such as the one at Chernobyl, the resumption by some countries of atmospheric nuclear bomb tests, and possible health and environmental threats from aging nuclear-powered satellites in decaying orbits.

While this program evaluation study was in progress, RPB commissioned a review of its National Radioactivity Monitoring Network and Reactor Monitor Network by an independent consulting firm.[59] PED has examined the review report and believes that review has satisfactorily addressed the concerns raised during the program evaluation about the program's ability to respond to nuclear emergencies.

3.3 CONCLUSIONS

According to the evidence available to PED for this evaluation, RPB has been effective in administering the Radiation Emitting Devices Act and Regulations.

RPB uses the Departmental risk assessment and risk management framework not only in the annual planning and resourcing of its activities but also in unplanned requests that come as part of their advisory responsibilities to other clients and stakeholders.

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[59] *Review of the National Radioactivity Monitoring Network and Reactor Monitor Network.* Prepared for Health Canada by Beak Consultants Limited, July 1995, contract no. H4078-4-C598/01-SS.

> RPB technical expertise in the area of ionizing and non-ionizing radiation is well recognized and sought.
>
> RPB appears to have an adequate system for identifying and assessing high-risk devices. The Bureau, however, does not have either a pre-market or post-market surveillance system of these devices, mainly due to lack of resources and budgetary restrictions that such a system would require. PED did not find evidence of significant risks from radiation emitting devices that EHD was unable to manage adequately. RPB maintains a list of radiation-emitting devices and conducts inspections of radiation emitting devices in federal facilities. The Bureau also conducts evaluations/investigations and surveys of radiation emitting devices.
>
> Generally, industries and institutions are in compliance with the regulatory actions and decisions taken under the Radiation Emitting Devices Act. There are no major problems with the enforcement of these actions and decisions.

The RED Act has served the Canadian public well. Some Program officials think that a review of the Act might be in order. However, interviews with external Program clients and stakeholders did not reveal any concerns about the RED Act and Regulations.

The Theratronics case study suggests that current legislation may not provide adequate protection for human health. The consultants recommend that RPB explore, in concert with other regulatory entities (both within Health Canada and outside), the possibilities of providing more regulatory attention to the protection of human health from radiation-therapy devices. PED shares some of the consulting firm's concerns on the subject of whether patient safety is sufficiently protected with radiation-therapy devices; the consulting report serves to flag these concerns for attention. However, the issue of which jurisdiction or jurisdictions have or should have responsibility in this area is complex, as is the issue of appropriate allocation of scarce RPB resources among competing health-risk priorities. The ultimate judgment on the appropriate additional action to be taken, or not, rests with the professional staff and management of RPB.

4. OTHER HEALTH RISK COMMUNICATION AND ADVICE

This section examines how effectively the Environmental Hazards Program (EHP) communicates with specific interest groups and with the public about actual public exposure to radiation and chemical hazards, and known health risks from such exposure. It also examines how the EHP provides information and advice on the management of health risks from environmental sources, beyond its activities under CEPA and the RED Act.

4.1 Background

In the area of risk communication, the Environmental Hazards Program's expected results focus on more-informed decision-making by workers and the public regarding health risks from the environment and hazardous products.

Risk communication and risk perception play an important role in the EHD's communication plans. These are areas where EHD and the Health Protection Branch have dedicated a great deal of research and effort. These terms as used in the Branch [Health and Welfare Canada (January 1990)] are defined as:

> "Risk communication is the exchange or provision of information to inform, persuade, or warn others about risks to health. More specifically risk communication is the act of conveying or transmitting information between interested parties about levels of health or environmental risks; the significance or meaning of such risks; or decisions, actions, or policies aimed at managing or controlling such risks. Interested parties include government agencies, corporations and industry groups, unions, the media, scientists, professional organizations, public interest groups, and individual citizens".
>
> "Risk perception is an impression or intuitive judgment about the nature and magnitude of a health risk. Perception of risk involve the judgments people make when they are asked to characterize and evaluate substances and activities".

Various HPB studies give high priority to the linkages between public perception of risk and effective risk communication. The flows and linkages between the domains of perceived risk and technically-assessed risk are shown in Figure 4 below (The Communications Processes Model), which is reproduced from the Review of Risk Communications Practices of the Health Protection Branch study [Leiss, William (1989)]. Leiss stresses the importance of public participation, consultation, and the evaluation of risk communication strategies as part of the option analysis, monitoring and evaluation phases of the risk assessment and risk management framework.

The Branch considers effective risk communication to be an essential link between government and public responsibility for risk assessment and risk management in health protection. The following paragraphs reflect the Branch's views on effective risk communication [Leiss, William (1989)], p. 8].

INSERT FIGURE 4 HERE

> "As scientists, we must strive to present the results of our studies of health and environmental risks in terms that can be readily understood by both health professionals and the general public".
>
> "As regulatory authorities charged with the responsibility of making critical public health decisions, we must establish meaningful channels of communication with those affected by such decisions and secure their involvement in the decision making process itself".
>
> "As members of the public, we must seek to make our views on risk known so as to fulfil our responsibility to participate in societal decisions of risk".

Recently, under EHD's leadership, the Branch drafted a report entitled Health Risk Communication Handbook [Health Canada (March 1994)]. The purpose of the handbook is to provide guidance on how to formulate messages for both *impromptu* and *planned* risk communications. The handbook's objectives of effective risk communication are not only to facilitate the exchange of needed information amongst all interested parties, but also -- at least in some cases -- to seek to change attitudes and behaviour in the light of knowledge about health risks. In other words, in ideal circumstances, risk communication seeks to be proactive rather than reactive. The Handbook suggests evaluation and feedback to address the effectiveness of risk communication.

The communication of information about health risks and their management is a function the Environmental Health Directorate (EHD) shares with other organizations within Health Canada, notably Communications Directorate, Policy and Consultation Branch and the Health Promotion Directorate, Health Programs and Services Branch[60] (HPSB). Figure 5 below shows the relationship of EHD with the Communications Directorate and HPSB.

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[60] At the time of the evaluation the Branch was being reorganized, the functions and name of the former Health Promotion Directorate have been changed. The new name of the Branch is the Health Promotion and Programs Branch.

INSERT FIGURE 5 HERE

While EHD links some of its communication activities with the Health Promotion Directorate, EHD has operational communication linkages with the Communications Directorate, Policy and Consultation Branch (P&CB). Under the Director of Planning and Operations, the Communication Directorate assigns Communications Executives to all the Departmental program Branches, and Communication Officers to each Directorate within a Branch. The role of the Environmental Health Directorate's Communications Officer is to:

- support EHD's communication needs by dealing with various officers, chiefs and directors;
- participate in the preparation of Issue papers of the Directorate;
- prepare program people to deal with the media;
- maintain current media coverage of EHD's related issues;
- provide his/her clients in EHD with a broader picture of government communications priorities; and
- other communication products such as videos, press releases and ministerial announcements.

EHD also has a Publications Coordinator who is in charge of the production of all EHD publications. The EHD's publication Coordinator controls all of the stages of an EHD publication, from the development, printing, to the Ministerial concurrence of the publication. In its continuing efforts to serve and maintain contact with its stakeholder and the general public, EHD has currently under construction a home page in the Internet. This home page will contain a more complete profile of the Directorate, including EHD's general information, technical publications, and newsletters. EHD's Publication Coordinator is now the information management contact in Internet.

As part of their risk assessment and risk management activities, the EHD's Bureaux conduct annual reviews of their project areas, called Project Area Reviews (PARs). Most of EHD's communication activities are described in the communication plans of its PARs.

The communication plans concerning chemical and radiation hazards include the production of:

- publications, including draft regulations and amendments, safety codes and guidelines, information and alert letters, journal publications, abstracts, proceedings, reports, papers, issue papers, pamphlets;

- presentations, including conferences, lectures, workshops, training courses and both on and off-site client consultations and instruction, video-tapes, TV productions and displays;

- electronic media (e-mail) and computer bulletin boards.

Most of EHD's communication products, although available to the general public, are aimed at relatively small groups of interested readers, mostly professionals working in a specialized field.

The following evaluation findings are based on several sources of evidence: PED interviews with Health Canada officials; interviews and a mail survey conducted with non-Health-Canada officials and stakeholder [Resource Futures International and The ARA Consulting Group (May 24, 1995)]; four case studies prepared by Michael Holliday and Associates and PED's review of selected documents.

4.2 PED INTERVIEWS WITH HEALTH CANADA OFFICIALS

Health Risk Communication with the public. *EHP's health risk communication with the public is not as effective as with its immediate clients.*

Most program officials told PED they believe the Environmental Health Directorate (EHP) has done a good job of communicating to scientific peers and Departmental clients. However, program officials also stated they believe they have been less effective in communicating with the public. Several said communication with the public is probably one of the weakest aspects of the Environmental Hazards Program, the notable exceptions cited being the Great Lakes Health Effects Program and a few specific publications, such as "The Sun, Your Baby and You." Officials gave several reasons for weaknesses in the program's ability to communicate with the public.

Program officials perceive the publication approval process in Health Canada to be overly time-consuming and bureaucratic, making it difficult to get timely publications to the public.

Turnover among communications personnel devoted to the program has been high. At the time of the evaluation interviews, the Communication Executive at the Health Protection Branch was on maternity leave with no replacement having been appointed; the EHD's Communication Officer had been recently appointed and was still learning about the Directorate. Most recently, the Director of Planning and Operations, Policy and Consultation Branch (P&CB) has moved to another job within the Public Service, contributing further to a lack of continuity in the function.

There is friction between the Communications Directorate and EHD. For example, one of the interviewees commented that "the Communication Director does not usually inform EHD when they change the Communications Officer". At the time of our interviews few Program Officials knew of the appointment of the new EHD Communication Officer. EHD on occasions has to use its Publication Coordinator to perform the duties of its Communications Officer. There is also frustration in EHD with the responsiveness of Communications Directorate (P&CB) to EHD requests for assistance from them. For example, in December 1994, EHD needed to get separate product alerts issued on the same day to the public on pacifiers and pacemakers, but was told by the Communications Directorate the latter could not handle two product alerts recalls on the same day.

Several interviewees told PED they believe there is not enough coordination of the Program with Health Promotion Directorate, saying there should be formal links between EHD and Health Promotion Directorate. There do appear to be good linkages between GLHEP and Health Promotion Division at the working level, however.

The recently drafted Risk Communication Handbook [Health Canada (March 1995)] states that ideally public risk communication be proactive rather than reactive. In every day work, however, program officials often do not know what information the public wants, saying their involvement with clients is generally reactive rather than proactive. Program officials indicated the public and stakeholder participation is often absent from EHP risk communication initiatives, though there are exceptions to this (e.g., consultations with stakeholders on the wording of health risk messages concerning solar ultraviolet radiation).

Several interviewees said the Program does not have enough indicators to measure the effectiveness of its risk communications. However, the recently drafted Risk Communication Handbook [Health Canada (March 1995)] contains some good ideas on how to evaluate the effectiveness of risk communications.

Some officials noted in our interviews with them that EHP officials should be more sensitive to the need for planning communications; not all the problems with communication to the public should be attributed to Communications officers. For Communications input to be effective, the Communication Officer has to be involved in the planning of those documents, projects, and issues that have a public communications aspect. Sometimes Program officials neglect the communications aspect until the last minute, resulting in inadequate time for proper input from the Communication Officer. Health Canada Communications Policy requires concurrence forms to be signed by the ADM in the case of publications and by the Minister in case of Press Releases; the preparation and processing of these forms takes time, and early notice to and involvement of the Communications Officer could expedite the process.

Officials believe EHP's greatest successes have occurred through partnership efforts with outside organizations, e.g., the pamphlet "The Sun, Your Baby and You." EHD needs to strengthen and dedicate financial resources to building such partnerships and alternate distribution mechanisms such as electronic distribution, perhaps through Internet. They added that cost-recovery and revenue generation could also play a major role in effective communication and marketing.

Health Risk communication with immediate clients. *Health risk communication with immediate clients is usually done promptly and is considered reliable:*

Program officials told PED they provide reliable and useful information to their immediate clients, usually quickly. Many EHP scientists communicate directly with scientific colleagues on Internet, though these communications are limited to known contacts with whom they have had past dealings. On occasions, some officials noted the program tends to be more reactive than proactive in its communications and advice, due to resource limitations.

The assessment of the importance and timeliness of EHD as a source of information was echoed by program clients in other parts of Health Canada.

> PED was told the EHP meets Medical Services Branch's needs promptly, are responsive and helpful, have good people on staff, take the issues seriously and delve into them with enthusiasm. As a service delivery organization, MSB much appreciates the client service orientation of EHP.
>
> Health Promotion Division (HPD) staff report having no difficulty getting information when they ask for it and clear explanations of the technical information EHD provides them. In many cases, if HPD receives a request from a community-based program, the HPD staff will refer the caller directly to Bureau staff in the EHD.
>
> Information EHD provides to LCDC is seen as timely and up to date. Among other things, research advice provided on the radiation effects from tanning beds was of high quality and useful.
>
> When Foods Directorate has asked EHD for information or advice, EHD's responses have been seen as timely and useful.
>
> A Regional interviewee told the PED interview team the advice sought and received from EHD has been adequate on the whole. However, there is a concern about how "thin on the ground" resources are in some specialized areas, specifically in RPB. In some areas the Program only has one expert on staff. If there should arise two or three emergencies across the country at the same time in one of these fields, timely responses

could be problematic; no specific instances of this actually happening were cited. RPB officials separately expressed this same concern to PED. Given the highly specialized nature of the expertise and government-wide limits on funding and staffing, PED sees little option but to accept the risks to timeliness in such cases.

EHP's Health Risk Communication and Advice Essential *EHP's health risk communication and advice is considered essential and unique.*

Program officials told PED that some EHD risk management projects are unique to EHD and have no replacement. Examples officials cited were the caribou meat project[61] with Food Directorate and Medical Services Branch, and the GLHEP. Program officials suggested an alternative information source on chemical substances would be the chemical industry, but information from the industry is biased or would be seen by the public as biased.

Program officials told us some chemical-assessment expertise is available in Ontario, Alberta and Quebec, but very little in other provinces. It would not be cost-effective to have CEPA assessment work done in the Provinces, due to duplication of expertise and loss of economies of scale and critical mass for this work. In the absence of BCH, clients would have to turn to the US or Europe for information. The needed expertise and ability to integrate it into a risk-management framework is not available outside of BCH anywhere in Canada. The Canadian academic environmental health centres are small and rely heavily on EHD for information and funding.

If Canadians want Canadian data, advice and standards on environmental health risks, they need EHD. Canada needs the EHP to balance the risks to health with the economic benefits of chemicals. Data are available from the World Health Organization (WHO) and US information sources, but these may not be applicable or appropriate to the Canadian environmental context. Canadians often are exposed to different mixes or different contaminants altogether, and the way these affect health can be very different due to environmental differences in Canada. Canada needs a national, Canadian perspective and expertise to integrate the science and health data. Furthermore, offshore information sources have no mandate or requirement to respond to requests, and their responses to Canadian queries could be late and expensive. Much of what EHD does is cost-effective nationally and would be a prohibitive cost burden on the taxpayer if done separately by ten provinces and two territories, especially as many provinces simply do not have the expertise or resources at all.

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[61] This project is part of the Northern and Arctic Contaminants Initiative under the Action Plan on Health and the Environment. Caribou organ meat and various species of fish have been shown to contain potentially significant amounts of contaminants, but accurate health hazard assessment has in the past been limited by the gaps in knowledge of consumption levels among members of First Nations people. The purpose of the project is collect such information and to provide information to First Nations people on consumption levels that would keep exposure to these contaminants within safe limits.

A senior program official also observed that EHD only generates a relatively small amount of scientific information itself, drawing extensively on international literature. Others can use this literature if they know where to find it and how to interpret it. EHD's value added is as an informed filter, tailoring information to client needs and specific questions on health. EHD generates a lot of valuable knowledge (as opposed to information) that would not otherwise be generated.

4.3 RFI Interviews with other Federal Government Stakeholder

In summarizing the replies by 48 interviewees, RFI reported "clients rate EHD advice and information as timely and useful and feel that there is no alternative to what is considered to be a valuable and essential national service and support."[62]

However, the report suggests perceptions of EHP's advice and information vary between those interviewees with close working relationships with EHD and those "not in close proximity" to the program. Many of the latter "may not know the existence of information or who to ask for such information. In contrast, the internal (proximate) audience knows what exists and who to contact. The remedy, it was suggested, is to reach out to communities and publics rather than simply traditional health professionals; but this, it was added, is not what scientists do well. It was also suggested that EHP needs to package information better for decision-makers and policy types in local groups and communities. . . . Information, both advice and published materials, is by and large viewed as timely and useful ... Timeliness of course depends on the urgency of the issue in question and the corresponding expectations of the recipient; however, the general feeling is that if the situation is urgent, the information required is provided in a timely fashion."[63] The report suggests there may be problems in following up on issue advisories with local decision makers, once the advisory is issued.

Focusing specifically on information provision to the small number of RPB stakeholders interviewed, RFI found that "because radiation protection is a matter of inherent concern, there is a need for information. Continued efforts, it is felt, are required to inform and educate target populations. More to the point, relevant information needs to get to the right people (a recommendation made in reference not only to radiation protection but also other EHP communications). A problem which arises in large medical institutions, for instance, is staff turnover"[64] which reinforces the need for continued or repeated communications on radiation (and perhaps other) hazards; it cannot be assumed that new staff will necessarily find and read the communications their predecessors received from EHD.

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[62] Resource Futures International (RFI) and the ARA Consulting Group Incorporated (May 24, 1995). *Environmental Hazards Program Evaluation Interviews, Mail Survey and Indicators Workshop: Final Report*, page iii. This report is referenced hereafter as "RFI" in further footnotes of the report.

[63] Ibid., p. 13.

The Great Lakes Health Effect Program was reported to be the exception in its effective public communications . GLHEP is viewed as increasingly reaching out to communities and to the public. GLHEP was also given as an example of the more proactive approach which it is suggested EHD needs to take -- to provide not only scientific advice, but also information on what the public can do to help manage health risks from the environment.

RFI's report notes that EHD's problem in communication arises from two objectives that, if not conflicting, at least require different skills - the provision of scientific advice to a set of sophisticated and well-informed clients, and outreach communications to the general public.

4.4 Mail Survey of Stakeholder and Clients [Resource Futures International and the ARA Consulting Group Incorporated (May 24, 1995)]

EHP officials told PED they get 52,800 requests per year for information on environmental hazards to health and related matters (48,000 to the Department's Communications Directorate and 4,800 to EHD itself). The same source told us that about 20% of all requests for health information from the Department are related to environmental hazards. The most immediate clients for the program are those whose representatives were interviewed by RFI; the much larger body of more indirect or infrequent clients is harder to identify and reach.

Unfortunately, the Department has no single mailing list or data base containing the names, addresses and subjects of information requests. PED experienced considerable difficulty compiling, with EHD and HPB's help, a single address list for the persons and organizations from whom the program received information requests.

> In the course of preparing this mailing list, PED became aware there really are no well-maintained mechanisms in EHD or in HPB for identifying, recording and tracking clients and stakeholder requesting information, with the exception of federal or provincial departmental and committee clients. There was no single, readily accessible computerized mailing list or data base from which one could readily identify clients who have requested or received publications or other formal information from program officials. In PED's view, the absence of such a list or data base seriously impairs the program's ability to plan, conduct and evaluate risk communication plans and strategies.

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[64] Ibid., p. 10.

RFI and ARA Consulting Group conducted a mail survey of persons whose addresses were sampled from the list PED eventually was able to compile. As RFI details in the appended consulting report, the responses about the information provided to interviewees are on the whole very different from the responses provided by the mail-survey respondents.

The mail survey of 319 respondents painted a somewhat less positive picture of information provision than did the interviews. The findings were consistent across the two sources of addresses, both the less-focused HPB mailing list and the more-focused lists of key stakeholders provided to us by BCH and RPB officials. RFI reported to us the following survey findings.

> "There is only moderate awareness of the EHP and its activities or communications products among our survey samples, and correspondingly little use of many EHP information products and services. However, when the products and services were actually used, they appeared to be moderately useful, and a modest proportion of communications were very useful. Furthermore, many people thought EHP was working in areas relevant to their organization and would like more information about the program. ... A significant amount of EHP's communications is judged not very useful, even for respondents with a high level of interest in specific environmental health areas. The reasons for this are not known, and the analysis of the open-ended comments was not particularly enlightening. The technical quality of the communications seems to be reasonably good, although with room for improvement, perhaps especially for technical experts."
>
> "There is, however, some indication of inefficiency of distribution: the most important people may not always be reached, and some of the people reached have only a passing interest in EHP products. If one assumes that the mailing lists provided represent people who would truly get value from its publications, then there is clearly room for improvement in the manner in which EHP informs its audiences about its activities and products, and distributes this information and these products."[65]

The more removed informants are from the EHP, the less likely they are to express a view of the program as a unique and irreplaceable asset to Canadians. RFI found in its interviews that "opinions were mixed as to the existence of alternative sources for EHD-type information ... for many, there is no source of expertise or information comparable to, or which could replace, that provided by EHD. ... These opinions are once again held by those ... working in collaboration with EHD. As one provincial representative remarked, (EHD) is a valuable national service and support to the provinces. The same individual also noted that one has to have the capacity and knowledge to use the expertise available from EHD."[66] Other informants "said they have no dealings with EHD, that they could obtain the information they require elsewhere, and that they would not be bothered if the Program ceased to exist. In many instances, however, one is left wondering if, unbeknownst to them, the information which they state they can acquire elsewhere in fact has its origins in (the program)."[67] These latter views were most common among respondents to the RFI mail survey, many of whom, while interested, knowledgeable and active in environmental health issues, were even further removed from regular dealings with the Program.

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[65] Ibid., p. 29-31 *passim*.

Though RFI's interviews and its subcontracted mail survey were conducted and written separately, the consultants working on both parts of the contract independently concluded the program needs to review the focus of its advice and communications with non-proximate clients and the public. "Clients (interviewed) rate EHD advice and information as timely and useful and feel that there is no alternative to what is considered to be a valuable and essential national service and support." However, "neither the Directorate nor the Program have much profile in the public domain. This finding raises a fundamental question which was not explored; namely, how does EHD in fact wish to position the Program, and what are the corresponding communications objectives and strategies?" [68] The mail survey reinforced this fundamental question as follows: "Ideally, the EHP should provide products and services that are in some way unique; for example, a uniquely Canadian focus and interpretation; the most timely information through electronic means; the best personal servicing of requests; the integration of research and information activities of all relevant Canadian agencies; and so forth. Without such a unique focus, the EHP runs the danger of providing information that is only (seen to be) 'nice to have,' but not essential."[69]

Some stakeholder and members of the public, particularly those who do not interact frequently with the Program, do not recognize the name of the Program or associate its communication products with it. This lack of recognition arises from the program's low public profile. There are very few documents produced with the explicit identification either of the Environmental Hazards Program or the Environmental Health Directorate. The Program's publications are generally occasional publications; unlike some other Directorates in HPB, EHD does not have any periodical publication with which the public and stakeholder could identify the Program. This lack of recognition can hinder the Program from getting more favourable ratings in client and stakeholder surveys; ultimately it may also have adverse implications for budget-cutting decisions made by officials unaware of the nature and value of the Program's communications activities. However, as Park and Holliday noted in their discussion of the UV program (see below), it is a moot point whether this lack of recognition matters in persuading Canadians to take the appropriate risk-management measures being communicated.

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[66] Ibid., p. 13.

[67] Ibid., pp. 13-14.

[68] Ibid., p. 16.

[69] Ibid., p. 31.

4.5 CASE STUDIES

The Holliday and Associates case studies provide another line of evidence on the question of information provision. The case studies reinforce the RFI finding that agencies and other stakeholders in direct contact with the program tend to receive very good and timely advice and information from the program.

Great Lakes Health Effects Program (GLHEP) Case Study [Park et al. (March 15, 1995)]

The case study by Holliday and Associates reinforced the perception that of all EHP programs, GLHEP seems to be the most successful in communicating with the public and in having public participation in their risk communication activities. GLHEP's explicit aim is to communicate with the public. The case study found that GLHEP has made considerable efforts to ensure that information and advice reach its "target" groups effectively. Some of these efforts include participating in Town Hall meetings convened by local authorities and the holding of workshops with various interest groups, which enable public perceptions and concerns about environmental health risks to be addressed directly.

> "It appears that the GLHEP is the most effective, and in many areas, perhaps the primary Canadian source of health-related information and advice on matters relating to the Great Lakes basin. The quality of such information was generally regarded as high by recipients, with the occasional reservation that the presentation is somewhat too technical for its intended audience -- a common criticism of such information for all sources."[70]

PED's review of an evaluation of a GLHEP's operations by the City of Toronto Pubic Health Department's Environmental Protection Office supports a generally positive assessment of GLHEP's provision of advice and information.

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[70] Park, John, Michael Holliday and Catherine E. Vardy (March 15, 1995). *The Great Lakes Health Effects Program: A case Study*, pp. 9-10.

In the area of Risk Assessment, GLHEP communicates with both the public and with other agencies. In each case, the Program acts as both a source and a two-way channel of information related to hazard identification and risk assessment.

CEPA Case Study [Park et al. (March 24, 1995)]

Communication to the public on CEPA assessments is arguably a special case, as Park, Holliday and Vardy reported in their consulting report to PED.[71] "The statutory requirements (under the Act) for public communication of CEPA-related material are limited ... Health Canada has gone beyond these statutory requirements ..." by making background documentation publicly available (as well as the assessment reports themselves), within the five-year time limit for almost all the PSL I substances. "The EHD has made considerable effort to communicate the aims and achievements of CEPA to the public, via a series of Issues papers, briefing documents and press releases."

The EHD is also preparing a *Health Risk Communication Handbook* to assist officials in communicating to the public on environmental health risks. One respondent, however, expressed regret at the low media and public interest in the toxicity assessment reports and newsletters and the absence of questions of the Minister in the House of Commons (though the Minister had been briefed on the subject "copiously"). This partly may have resulted from competition in the media at the time of the CEPA report releases from the issue of tobacco smuggling and tobacco excise taxes. The report questions whether a more proactive communication approach would have justifiable in any case, given the absence of "'practical' consequences from the assessments" as the control options had not yet been developed and public participation in the development of these options may itself serve as a communications avenue.

Theratronics Case Study [Gunther et al. (March 22, 1995)]

This case study addressed the communication activities of RPB with regard to cobalt 60 teletherapy equipment and treatment planning systems. The case study found that RPB communication role with regard to the cobalt 60 was that of an "information broker". As such RPB refers the users to the appropriate provincial authorities or, if the problem is one of equipment design, RPB contacts the manufacturer to ensure that the problem is resolved. RPB does not directly communicate with patients being treated with this equipment, nor does it have a statutory mandate to do so. In this case, RPB risk communication activities were mainly directed to its Departmental client, the former Field Operations Directorate (FOD). FOD asked RPB to produce a document stating the conditions under which the manufacturer could resume shipment of the cobalt 60 equipment (voluntarily ceased as a result of FOD and US FDA interventions initially not involving RPB), which RPB did.

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[71] Park, John, Catherine E. Vardy, and Michael Holliday (March 24, 1995). *Assessments and the Priority Substance List Under the Canadian Environmental Protection Act*, pp. 28-30 *passim*.

Often RPB's risk communication activities with clients and stakeholder is reactive, resulting from unexpected problems and crises. Under these circumstances, and in particular in the case study examined, RPB risk communication efforts do not include the full range of activities under the risk management framework. The case study suggests full use of that framework occur before problems arise, rather than afterward, but program officials point out this would require pre-market clearance and post-market surveillance activities beyond RPB's current resources.

Gunter and Holliday concluded in their case study concerning Theratronics products, "the (RPB) communicated promptly to the (former Field Operations Directorate) when their advice was requested, and their technical reports were of a high quality, demonstrating an in-depth knowledge of the equipment and the requirements of the treatment centres."[72]

UV Program Case Study [Park et al. (March 17, 1995)]

This case study reported that communications with government bodies and the public are the major activities of the UV Program. In the case of the UV-Index ™ program, RPB was a health-advisor, mainly through consultations by telephone and document review, but also through lectures and presentations. RPB advice is considered valuable and timely and essential.

The case study reports that the UV Program's first major communications were made indirectly through Environment Canada's UV program. RPB has subsequently made efforts to communicate directly with the public. One of RPB's most successful UV Program products has been the booklet The Sun, Your Baby and You, two million copies of which were distributed. It was also published by MacLean-Hunter. More recently, the Canadian Dermatology Association has been producing risk communication materials for the public, using information provided by the Department and by RPB.

Park and Holliday reported that RPB's advice to the Atmospheric Environment Service on the health effects of solar ultraviolet radiation to be "valuable and timely; and such a source of information is essential; otherwise, AES would have to turn to stakeholders, without guarantee that the information provided would be impartial and appropriate for government use." [73] In the appendix to their report, Park and Holliday report a third-party observation that "the publishing house, MacLean-Hunter, commented that the (program's) booklet *The Sun, Your Baby and You* was the most successful initiative of its kind the company had seen." [74] However, Park and Holliday echoed RFI's concern about the public profile of EHD programs: "It is a moot point whether this invisibility is detrimental to persuading Canadians to reduce their exposure to UV radiation, but Health Canada may wish to ask itself how the success of the Environmental UV Program is to be judged if the instigating body remains unrecognized by the targets of its activities."[75]

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[72] Gunter, Alfred W. and Michael Holliday (March 22, 1995). *The Bureau of Radiation and Medical Devices Response to Problems with Theratronics Products: A Case Study*, p. 38.

4.6 CONCLUSIONS

EHD has included in its Project Area Reviews communication plans that are annually monitored. EHD has commissioned research in the area of risk communication and risk perception and recently led the drafting of a Handbook on Health Risk Communication. Interviews conducted for this evaluation reveal that EHP officials have been successful in communicating with their peers and specific client groups.

The evidence PED has examined indicates the Environmental Hazards program is on the whole successful in providing timely and useful information and advice to the immediate clients and stakeholders whom PED and RFI interviewed. The results of the mail survey of somewhat more removed clients and stakeholders suggest the program can improve its risk communication efforts with this broader clientele.

PED concludes the Program's direct advice and information to federal Departments, agencies, governments and other immediate clients is a valuable and essential national service for which there is no realistic alternative.

PED concludes there would be benefits for EHD to plan and coordinate its communications objectives and strategies with its colleagues elsewhere in the Department, notably in Communications Directorate, Health Promotion Directorate, and LCDC. However, coordination requires mutual effort; EHP officials expressed to us considerable frustration in trying to deal with Communications Directorate in particular. EHD's involvements with Health

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[73] Park John M. and Michael Holliday (March 17, 1995). *The Environmental UV Program: A Case Study*, p. 18.

[74] Ibid., p. 33.

[75] Ibid., p. 21.

Promotion Directorate and LCDC seem to have been more positive, though somewhat limited terms of developing communications strategies jointly.

The Program presently has no formal mechanism for monitoring the effectiveness of its communications with the public, other than ad-hoc surveys on specific issues or publications. More formal monitoring and analysis of the effectiveness of communications and publications might indicate areas for improvement.

Both of the consulting firms contracted by PED to collect information on aspects of EHP operations independently concluded the program may be suffering from a lack of profile for its activities. From their mail survey, RFI and ARA Consulting Group concluded:

> "Our primary impression is that there are no clear distinguishing features which make the EHP activities and communications products different from, or better than, those of other organizations. In services and social marketing terms, this is referred to as perceptual positioning. The open-ended comments (by survey respondents) were the most illuminating on this score -- but because of what they did **not** say, not what they did! The scarcity and lack of detail in these comments is, in our experience, quite unusual; in other evaluations, many respondents who comment on programs they find useful go to considerable lengths praising the uniqueness, value, and importance of the programs' benefits. Often they attach separate pages extolling the program's virtues. Virtually no one did so (in this survey)."[76] This is in marked contrast with the findings of the interviews conducted by RFI: "...it is important to note the unsolicited comments made by many interviewees regarding their dealings with particular individuals with EHD. On frequent occasions, mention was made of highly satisfactory dealings with the likes of (several EHD scientists) and the professional respect in which these individuals are held."[77]

Roughly two-thirds of the respondents to the survey were persons whose addresses were on a Health Protection Branch data bases indicating they had expressed an interest in receiving information by mail from the Branch on chemical or radiation hazards. Many of these particular respondents have had little or no direct involvement with the EHP, and PED was told by Branch and program officials that EHD rarely, if ever, has used that data base for mailing information (which may in itself be a problem with the Branch's communications strategy). However, the names and addresses of the remaining third of the survey respondents were persons the Bureaux considered to be important external clients with whom they have had communications or dealings in the past. The cross-tabulations in the RFI report do not show any major differences between these two groups of respondents in their responses to the survey questions cited above.

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[76] RFI, op. cit., p. 31.

[77] Ibid., p. 6.

Many of the alternative sources of information survey respondents suggested they would turn to, if EHP no longer provided information, are sources which themselves rely heavily on information and advice from the EHP, something of which the survey respondents may not have been aware. This is akin to the "program invisibility" issue raised by Park and Holliday regarding the UV program.

Neither of the consulting firms appear to be suggesting the operations, information and advice provided by EHP are of questionable value, quite the contrary. However, they are suggesting that awareness of and support for EHP activities is limited to the program's most immediate constituencies, largely in other government departments and organization. The notable exception in this regard being the Great Lakes Health Effects Program, which as far as we can determine is very highly-regarded by the communities and community organizations in the Great Lakes Basin which have dealt with it.

In times of growing competition for shrinking public funds, managers of programs such as EHP cannot afford to maintain such a low profile among the public and other constituencies, whose support (or lack of it) could affect the funding decisions of politicians and senior government officials who have limited or no awareness of the program.

5. Protecting the Health of Canadians

This section examines the contributions the Environmental Hazards Program (EHP) has made to the health and safety of Canadians.

5.1 General Comments

RFI reported its interviews showed "the Directorate and the Program are believed to be making a significant contribution to the protection of the health and safety of Canadians from environmental hazards. This contribution, however, must be viewed in the context of the EHP in combination with other initiatives; i.e., not in isolation, but as value-added . . . Changes in (the public's risk-management) behaviour are the product of multiple initiatives, EHP and others, dealing with human health and the environment."[78]

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[78] RFI, op. cit., pp. iii and 12.

Given the diversity of environmental health hazards covered by the Program, it is difficult to make a global summary of Program contributions to protecting the health and safety of Canadians. In the abstract, one might like to estimate how many lives the Program has saved or prolonged, or perhaps estimate a dollar value of disease-and-disability-free days of life saved, and to compare these figures with the costs of the Program. In reality, the data and analytic techniques to do such calculations properly across the entire Program do not exist and perhaps never will, given the nature of the hazards, the latencies of their effects, and the often indirect impacts on health of many Program activities. Instead, PED presents below a few specific cases of contributions the Program has made. The list is not exhaustive and was suggested by various Program officials as "top-of-mind" examples of the value their program adds to the multiple initiatives referred to in the RFI report.

5.2 BUREAU OF CHEMICAL HAZARDS

There are several examples given to us by BCH officials of ways in which the EHP has helped to protect the health and safety of Canadians from hazards arising from exposure to chemical substances.

5.2.1 The health risk assessment work done by BCH under CEPA has significant potential health and cost implications for Canadians.

In their case study on CEPA assessments, Park et. al. estimate that applying a hypothetical control option to limit atmospheric benzene (a CEPA-toxic substance) from gasoline combustion might result in saving one statistical life per year. The paper suggests this notional saving of one life per year could cost the industry and the consumer $350 million a year.[79] The inference one might reasonably draw from such an estimate is that controls on emissions of this substance may be hard to justify on economic grounds.

A contrast can be drawn with cadmium, another CEPA-toxic substance, which persists in the human body and in the environment over relatively long periods of time. Cadmium levels in human tissue and in the environment are not cause for current concern. However, depending on the assumptions one makes about the rate at which cadmium builds up in soil and in tissue in the absence of any emission controls, in a few hundred years the levels could result in kidney failure among a significant portion of the adult population, which would have considerable health-care costs. It will be difficult and controversial to balance present-day economic costs of control options against potentially very expensive health effects that may only appear decades or even centuries from now if controls are not implemented. However, the analysis needs to be done.[80]

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[79] In a more recent paper, Holliday and Associates have revised this estimate downward to $100 million a year; see M. Holliday et.al., notes to an oral presentation to the World Environmental Congress September 17-22, 1995, "The Canadian Environmental Protection Act: Science, Policy, and Public Health." The point about the difficulty in justifying the hypothetical control option on economic grounds remains, in PED's view.

There are eighteen PSL I substances that were declared toxic, and benzene and cadmium are only two of them. The assessment and control-option analyses done by BCH under CEPA may have significant implications for short-term regulatory costs and long-term health effects on the population. BCH's work under CEPA is important to Canadians, and it is important it be done using the best science available.

5.2.2 The Great Lakes Health Effects Program (GLHEP), part of the operations of BCH, helps communities in the Great Lakes Basin understand the environmental health hazards their residents might be exposed to and what these communities can do to reduce or manage the risks to their health from these hazards. GLHEP has an external, community-based Advisory Committee which met to evaluate the program in 1992. [81] While the Advisory Committee had a number of recommendations for improving the program, its report stated:

> "Members were agreed that the quality of the projects undertaken in the program was commendable, particularly given its brief history. The goals and objectives of projects have been well delineated and the strong public participation component could serve as a model for other Health and Welfare Canada programs. The committee felt the management of the program and the quality of its findings have been consistently excellent."

Program officials consider GLHEP's first success story to be the community of Collingwood, Ontario. GLHEP worked with local business and community groups to fix their contamination problems, and the community is now de-listed (no longer considered an Area of Concern). The community did clean-up work the EHP could not have afforded to fund, but program advice, assistance and "leveraging" helped make the clean-up possible. GLHEP's ultimate objective is to work itself out of a job, helping all

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[80] A detailed discussion of the complexities of this analysis may be found in Holliday, M.G. and J. M. Park, "Canadian Kidney-cadmium Levels, Exposure, and Implications for Environmental Control," poster presentation, World Environmental Congress, London, Ontario, September 19, 1995.

[81] "Great Lakes Health Effects Program Advisory Committee: Program Evaluation and Recommendations," October 1992, submitted to GLHEP Division by Environmental Protection Office, Department of Public Health, City of Toronto.

Great Lakes Basin communities to take over long-term management of health risks from their environment. The ultimate success indicator for GLHEP would be the de-listing of all Areas of Concern, whereupon the program could be shut down.

5.2.3. The management of health risks from air pollution is a responsibility BCH shares with many other departments and governments. An important contribution of the Program is research into the health effects of air pollution, which could eventually translate into an understanding of the health-care cost implications of air pollution and help inform and support various risk management options. Air pollution in a particular city or province can affect thousands of Canadians to one extent or another; the effects can be fatal for some asthma patients, and for other Canadians can result in lost productivity due to impaired functioning, actual sick leave from work or even hospitalization. A recent publication by BCH staff summarizes the results of some of the Program's research: [82]

> "To investigate the acute respiratory health effects of ambient air pollution, the number of emergency or urgent daily respiratory admissions to 168 acute care hospitals in Ontario were related to estimates of exposure to ozone and sulphates in the vicinity of each hospital. Ozone levels were obtained from 22 monitoring stations maintained by the Ontario Ministry of the Environment for the period January 1, 1983 to December 31, 1988. Daily levels of sulphates were recorded at nine monitoring stations representing three different networks operated by the Ontario Ministry of the Environment and Environment Canada. Positive and statistically significant associations were found between hospital admissions and both ozone and sulphate recorded on the day of admission and up to 3 days prior to the date of admission. Five percent of daily respiratory admissions in the months of May to August were associated with ozone, with sulphates accounting for an additional 1% of these admissions. Ozone was a stronger predictor of admissions than sulphates. Positive and statistically significant ($p<0.05$) associations were observed between the ozone-sulphate pollution mix and admissions for asthma, chronic obstructive pulmonary disease, and infections. Positive associations were also found in all age groups, with the largest impact on infants (15% of admissions associated with the ozone-sulphate pollution mix) and the least effects on the elderly (4%). Temperature had no effect on the air pollution-admission relationship. Ozone (lagged 1 day) and sulphates (lagged 1 day) displayed a positive association with respiratory

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[82] "Effects of low ambient levels of ozone and sulphates on the frequency of respiratory admissions to Ontario hospitals," by R. Burnett, R. Dales, M. Raizenne, D. Krewski, P. Summers, G. Roberts, M. Raad-Young, T. Dann, and J. Brook. Environmental Research, 1994, Vol. 65, pp. 172-194.

> admissions for 91 and 100% of the 168 acute care hospitals, respectively. Air pollution was not related to a class of non-respiratory admissions, which served as a negative control, nor was it related to admissions in the winter months of December to March, when ozone and sulphate levels are low and when people spend a considerable amount of time indoors."

5.2.4 Canadians benefit from some of the cleanest, purest drinking water in the world. One often takes this for granted, until one travels abroad and discovers first-hand the acute risks of drinking tap water in some countries; there can also be long-term health implications from chemical pollution of drinking water.

The Bureau of Chemical Hazards contributes to the maintenance of the quality of Canada's drinking directly through regulatory actions under federal jurisdictions (Indian reserves, military bases, etc.) and indirectly in other jurisdictions in Canada (provinces and municipalities) through the development and promulgation of its Guidelines for Canadian Drinking Water Quality. Even though these guidelines are not legally binding unless formally adopted in legislation in a particular province, the courts have recognized them as standards which can be used to find private companies legally liable for polluting water even on private property, if the water eventually finds its way into a public water supply. BCH officials have testified as expert witnesses in court cases involving discharges of hazardous substances into ground water.[83] The jurisprudence in these cases further protects Canadians by establishing that every director or officer of a corporation has a duty to take all reasonable care to prevent the corporation from causing or permitting an unlawful discharge of hazardous substances into ground water.

5.3 RADIATION PROTECTION BUREAU

There are several examples given to us by RPB officials of ways in which the EHP has helped to protect the health and safety of Canadians from radiation hazards. RPB's work in the field of x-ray protection has resulted in significant reductions in the dosage of x-rays used in federally-run health facilities in remote areas, by dentists throughout Canada, and in orthopaedic physicians taking x-rays of the full spine of adolescent women suffering from scoliosis, as well as in x-ray examination of luggage at airports.

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[83] See, for example, Hearing Disposition Report #90-0088 (Legal Services Branch, Ontario Ministry of the Environment) and R. v. Bata Industries Ltd. et. al. (Ontario Court of Justice Provincial Division, February 7, 1992)

5.3.1 All Canadians benefit from a thirty-year reduction in patient radiation doses from dental radiography; an internal RPB study estimated that in 1988 a dental patient would receive only 10% of the radiation (s)he would have received in 1966 for the same procedure and only 2% of what would have been received for the same procedure in 1957.[84]

5.3.2 X-Ray Section, RPB provided PED with data from the radiation safety surveillance they perform in remote areas in Canada under the Treasury Board Standard and the Canada Labour Code. Data on representative chest x-ray skin entrance exposures at 44 small facilities in remote locations in Canada show more than a five-fold reduction in average exposure from 1975 to 1990-93. Thus, as the result of direct regulatory inspections of these federally-administered facilities, Canadians in these remote locations have benefited from a substantial reduction in their exposure to health hazards from x-rays. RPB's direct regulatory experience in this jurisdiction has no doubt enhanced and guided its advice, promotion and influence over x-radiation procedures governed under other jurisdictions.

5.3.3 Through its inspections and advice to Transport Canada, RPB has contributed to reducing the dosages in airport baggage x-ray machines in Canada without compromising the function of that equipment. The radiation doses from that equipment is now so low that the operators of that equipment are not considered to be x-ray workers and do not need dosimetry badges.

These reductions in x-radiation have been achieved at no loss of diagnostic information from the x-ray procedures. Reductions in radiation have resulted from RPB advice and promotion concerning the design of equipment (e.g., more accurate focusing and narrowing of x-ray beams), the use of equipment (e.g., proper positioning of the patient's body prior to beginning the dosage), replacement of old equipment, and the use of more sensitive x-ray film and screens (permitting the use of lower doses while still registering the same information).

Though direct attribution would be very difficult or impossible to measure through epidemiological research, given the latency periods and confounding factors involved, there can be little doubt reductions in x-radiation administered by physicians and dentists have averted cancers in patients across Canada. Much of these reductions resulted from the work and publicity of the Program, though (as with the operations of BCH) it would be difficult and probably futile to attempt to separate the contributions of the Program from the contributions of the efforts of the Program's partners in other federal departments, governments, the health-care professions, and various non-governmental organizations.

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[84] Lavoie, Christian, P.Eng. (undated). *Study of Conventional Dental X-Ray Equipment in the Ottawa Area.* Excerpt from internal report, X-Ray Section, Radiation Protection Bureau, Health Protection Branch.

However, PED agrees with RPB's belief that, for example, their efforts have resulted in diagnostic practices that in the long term greatly reduced the radiation to the breasts of scoliosis patients and the incidence of breast cancer among those young women. We also agree that changes in Canadians' sunbathing habits brought about in part by Health Canada publicity and the work of Radiation Protection Bureau concerning the risks from solar ultraviolet radiation may well result in a measurable decrease in melanoma in a relatively short period of time, though it is too early for such results to be detected statistically. Park and Holliday report an estimate of presently 580 Canadian deaths per year from malignant skin melanomas, so the potential savings in human lives is significant.

Reinforcing these contributions, RFI found in its interviews "the provinces rely on federal legislation, safety standards and codes as the benchmarks for design and functioning criteria for radiation emitting equipment. Provincial respondents reported that, in their experience, the RPB is 'readily available to respond to queries pertaining to radiation. Their expertise is frequently used.'"[85]

RPB's contributions to the health and well-being of Canadians are not limited to protecting Canadians from real health hazards; RPB also may have saved taxpayers millions of dollars in unnecessary health protection expenses, productivity losses, and opportunity costs.

- In the late 1970s and early 1980s there was much public controversy surrounding possible radiation and other hazards allegedly arising from prolonged exposure to visual display terminals (VDTs) for computers, word processors, and related electronic display devices. Because of these concerns, some argued pregnant women either should be excused from working near such devices or be provided with lead aprons; others argued there should be regulations limiting the amount of time VDT operators should be required to work near a VDT each day. (For example, see page 13 of the report of the Task Force on Microelectronics and Employment to the Minister of Labour, 1982.) Implementation of many of these recommendations would have been costly, both in regulatory costs and in lost productivity from VDT workers. It was important to know whether the health concerns were real and significant enough to justify the costs of the actions being proposed.

  Beginning in 1979 and throughout the 1980s, RPB conducted its own research and monitored the published research of others on the subject of health hazards from VDTs. As reported in the references cited below, RPB established beyond reasonable doubt that none of the suspected health effects from VDTs could be demonstrated scientifically. Long-term epidemiological research over ten years confirmed the lack of ill effects associated with the use of VDTs, whether from radiation (whether ionizing or non-ionizing), eye strain, or muscle strain. RPB continues to monitor the literature on VDTs to ensure no new or hitherto unsuspected health risks have emerged.[86]

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[85] RFI, op. cit., p. 10.

- Another good example of averting needless health protection costs through thorough research is the more recent work by scientists both in RPB and BCH on radon mitigation.[87] There had been extended controversy in the scientific literature and the popular press over whether radon entering North American homes through their basements posed a significant health risk that required potentially expensive interventions. The authors state in the study's abstract:

> "This paper examines the cost effectiveness of comprehensive strategies for reducing exposure to radon gas in indoor air in Canadian homes. The analysis is conducted within the context of a general framework for risk management program evaluation which includes well-known evaluation techniques such as cost effectiveness and cost-benefit analyses as special cases. Based on this analysis, it is clear that any comprehensive program to reduce exposure to environmental radon will be extremely expensive, and may not be justifiable in terms of health impact, particularly when considered in relation to other public health programs. Nonetheless, testing of homes at the point of sale and installing sub-slab suction equipment to reduce exposure to indoor radon where necessary appears to be a relatively cost-effective radon mitigation strategy. Because of regional differences in radon levels in Canada, radon mitigation will be more cost effective in some areas than others. In general, radon mitigation was found to be most effective in cities with relatively high levels of radon."

In the article's conclusion, the authors state "...it is clear that any comprehensive programme to reduce the levels of radon gas in (all) Canadian homes will be extremely expensive, with the total costs running into the hundred(s) of millions or even billions of dollars."[88] This research suggests such a comprehensive program would be unnecessary.

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[86] Sample publications by RPB staff on this topic include:

"Are video display terminals safe?" by Dr. E. G. Létourneau, CMA Journal, September 15, 1981, pp. 533-4.

"Low-background radiation measures on video display terminals," by C. Pomroy and L. Noel, Health Physics, 1984, Vol. 46, No. 2, pp 413-417

"Health aspects of work with visual display terminals," by Drs. I. Marriott and M. Stuchly, Journal of Occupational Medicine, 1986, Vol 28, No. 9, pp. 833-848.

[87] "Cost effectiveness of radon mitigation in Canada," by E. Létourneau, D. Krewski, J. Zielinski, and R. McGregor. Radiation Protection Dosimetry, 1992, Vol. 45 No.14, pp. 593-598.

As a result of this study, EHD was invited to sit on the USA National Science Committee of Biological Effects of Ionizing Radiation (BEIR) Committee. That committee's mandate is to make the best possible scientific statements whether or not radon in homes poses risk of lung cancer.

5.4 EHP'S INFLUENCE ON THE BEHAVIOUR OF INDUSTRIES, INSTITUTIONS, WORKERS AND THE PUBLIC.

One indicator of the influence of EHD is the regard other departments, governments and stakeholders have for the advice EHD provides to them. In its interviews with representatives of the program's clients and stakeholders, RFI found:

> "Health Canada in general, and EHD in particular, are applauded for what interviewees, by and large, regard as an objective, science-based approach taken to risk assessment. 'Credibility' was a word used often. ... Isolated comments include 'voice of reason' and 'it (EHD) puts health effects in the proper perspective and context.'"[89]

Program officials told us EHD-developed Canadian Drinking Water Guidelines have been incorporated into the water safety regulations of Ontario, Alberta, British Columbia and Quebec, as well as having been incorporated in the World Health Organization's drinking water guidelines.

RPB officials told us if their program were not in place, the federal government would have no credible opinion to express on environmental health risks when asked by the public, MPs, or the media. RPB provides the only integrated source of medical and scientific information in Canada on radiation risks to health. An example of potentially very expensive policies that could have been implemented in the absence of RPB advice to the contrary, is a nuclear tritium limit on nuclear-reactor water emissions that Ontario almost implemented. Limits proposed by anti-nuclear advocates would have been about 700,000 times lower than lowest international standards, much lower than background levels naturally occurring in Canada's lakes. These proposed limits were unjustifiable on a health-risk basis and could have resulted in all nuclear reactors in Ontario being needlessly shut down.

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[88] Ibid., p. 597.

[89] RFI, op. cit., p. 8.

The fact that something has been identified as being toxic discourages manufacturers from further production, and quietly moves the market to purchase substances that are safer to use. These intangibles have helped to contribute to reductions in overall risk. In this context, EHD does not need to regulate and still is able to achieve their objectives. For example, just having an HPB Issues publication on a particular topic, or declaring something toxic under CEPA, brings the issue into the forefront of industry and consumer interest groups. EHD officials cited anecdotal examples of companies complaining they have trouble selling certain chemicals now the public knows these are CEPA-toxic; people do not want to buy products containing substances that have been identified as being toxic to human health or to the environment.

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List of Appendices

(Available on request)

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